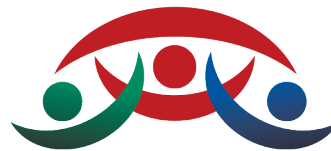


# INSPECTION STRATEGY

**Financial Year 2026–2027**





# OHSC

Office of Health Standards Compliance  
Ensuring quality and safety in health care

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## Inspection Strategy Report | 2026-27

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## **FOREWORD BY THE CHAIRPERSON**

The Office of Health Standards Compliance (OHSC), through its compliance inspectorate functions, continues to work towards providing high-quality, reliable, safe healthcare for the users of healthcare services in South Africa. The OHSC uses an incremental approach to develop inspection tools for different categories of health establishments (HEs), based on available financial and human resources. Inspections at other levels of care, including specialised health services, will be gradually introduced as the inspection tools become available.

The OHSC is dedicated to ensuring high-quality, reliable, and safe healthcare for users through its compliance inspection functions. The OHSC adopts an incremental approach to develop inspection tools tailored for different categories of HEs, depending on the available financial and human resources. Inspections at other levels of care, including specialised health services, will be gradually introduced as the inspection tools are made available.

The OHSC has developed and finalised eight (8) inspection tools to date. These tools for public health establishments include those for Primary Health Care (PHC) Clinics, Community Health Centres, District Hospitals, Regional Hospitals, and Tertiary and Central Hospitals. The private tools are designed for use by private acute hospitals and general practitioners (GPs). The finalisation of the Emergency Medical Services (EMS) inspection tool and the scoping of the mental health tool are underway, and their completion and implementation will place considerable demand on available resources.

During the financial year (FY) 2025/26, the OHSC finalised the General Practices (GPs) compliance inspection tool and used it to inspect 210 general practices across all nine provinces. This was a significant milestone towards increased inspection coverage at the primary health care level for the private HEs.

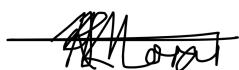
The Annual Inspection Strategy for FY 2026/27 outlines the Annual Performance Plan (APP) targets for 761 public health establishments and 210 private health establishments, for a total of 971 health establishments to be inspected. These targets are set in accordance with available resource capacity to conduct inspections. Inspections of private acute hospitals started in the 2022/23 FY, and all 208 private

acute hospitals in the OHSC's health establishment register have been inspected. The private sector inspection coverage target for 2026 to 2027 will cover 210 GPs.

During the 2025-2030 strategic planning period, the OHSC committed to improving inspection coverage by exploring the use of Artificial Intelligence (AI) technology referred to as "smart inspection", starting with virtual verification and pre-inspection document submission by HEs for verification in the 2026/27 financial year.

The implementation of smart inspections will be phased, with further technological advancements incorporated into inspectorate functions. The collaboration with stakeholders, including the National Health Quality Improvement Plan team (NHQIP), Provincial Departments of Health, Private Healthcare groups, respective HEs, and the National Health Insurance (NHI) division, will help improve compliance and the delivery of reliable, high-quality healthcare services across the country.

The OHSC inspected a total of 4990 (57%) health establishments in the country, from FY 2019/20 to 2025/26 including all 238 private hospitals and some HEs will be inspected for the second time from FY 2026/27. Despite significant operational and budgetary constraints, the OHSC achieved an inspection coverage of 812/799 (101%) and 975/971 (100.4%) across all planned categories of health establishments during the preceding financial years 2024/25 and 2025/26, respectively. The 2026/27 strategy builds on that foundation while introducing refined methods to improve coverage efficiency and strengthen risk responsiveness by conducting unannounced inspections.



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**Dr R L MORAR**

**OHSC BOARD CHAIRPERSON**

**DATE:** 12 June 2026

## OFFICIAL SIGN OFF

This certifies that the OHSC Inspection Strategy:

- It was developed by OHSC management under the guidance of the Board.
- Considered all applicable laws, regulations, and other directives that are pertinent to the OHSC.
- Represents the strategic, results-driven goals and objectives that the OHSC seeks to accomplish in the 2026/27 financial year.

  
\_\_\_\_\_  
**MR BONGINKOSI R KHUMALO**  
**DIRECTOR: COMPLIANCE INSPECTORATE**

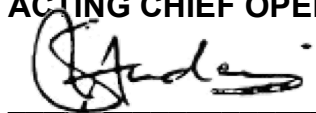
**DATE** 10/06/2026

  
\_\_\_\_\_  
**DR WINNIE MOLEKO**  
**EXECUTIVE MANAGER:**  
**HEALTH STANDARDS DESIGN, ANALYSIS AND SUPPORT**

**DATE** 10/06/2026

  
\_\_\_\_\_  
**MR TSOKODI NTSOANE**  
**ACTING CHIEF OPERATIONS OFFICER**

**DATE** 10/06/2026

  
\_\_\_\_\_  
**DR SIPHIWE MNDAWENI**  
**CHIEF EXECUTIVE OFFICER**

**DATE** 11/06/2026

  
\_\_\_\_\_  
**PROF LILIAN DUDLEY**  
**CHAIRPERSON:**  
**CERTIFICATION AND ENFORCEMENT COMMITTEE**

**DATE** 12/06/2026

  
\_\_\_\_\_  
**DR RL MORAR**  
**CHAIRPERSON OF THE OHSC BOARD**

**DATE** 12/06/2026

## LIST OF ABBREVIATIONS

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|              |                                                       |
|--------------|-------------------------------------------------------|
| <b>APP</b>   | Annual Performance Plan                               |
| <b>AR</b>    | Annual Returns                                        |
| <b>AI</b>    | Artificial Intelligence                               |
| <b>CHC</b>   | Community Health Centre                               |
| <b>EC</b>    | Eastern Cape                                          |
| <b>EMS</b>   | Emergency Medical Services                            |
| <b>EWS</b>   | Early Warning System                                  |
| <b>FY</b>    | Financial Year                                        |
| <b>GP</b>    | General Practice                                      |
| <b>HE</b>    | Health Establishment                                  |
| <b>KZN</b>   | KwaZulu-Natal                                         |
| <b>MEC</b>   | Member of the Executive Council                       |
| <b>MTEF</b>  | Medium Term Expenditure Framework                     |
| <b>NHA</b>   | National Health Amendment Act, 61 of 2003, as amended |
| <b>NHI</b>   | National Health Insurance Act, 20 of 2024             |
| <b>NHQIP</b> | National Health Quality Improvement Plan              |
| <b>OHSC</b>  | Office of Health Standards Compliance                 |
| <b>PFMA</b>  | Public Finance Management Act                         |
| <b>PHC</b>   | Primary Health Care                                   |
| <b>PPR</b>   | Pre-Preliminary Review                                |
| <b>PFR</b>   | Pre-Final Review                                      |

## DEFINITIONS

**Additional inspection /re-inspection selection** – Refers to the process of selecting previously inspected establishments for a follow-up inspection to verify whether the identified non-compliance has been remedied.

**Eligible establishment** - Refers to a health establishment that falls within the approved inspection scope for the year and is active, verifiable, and due or appropriate for inspection.

**Geographical cluster** - Refers to a group of health establishments located within the same district, sub-district, locality, or travel corridor and combined for inspection planning to improve logistical efficiency and enable analysis of shared system constraints.

**Inspection frame** - Refers to a verified list of eligible health establishments from which establishments are sampled or selected for inspection in a given financial year. An inspection frame is compiled from the OHSC register, annual returns, prior inspection records, and other validated OHSC data sources.

**Routine inspection selection:** Refers to the planned annual process of selecting eligible establishments for scheduled compliance inspections within the regulated inspection cycle and available APP targets.

**Risk-based inspection selection** - Refers to the process of selecting establishments for inspection based on risk triggers such as EWS alerts, complaints, Ombud findings, serious incidents, media reports, or other credible indicators of harm or material non-compliance.

**Replacement rule** - Refers to a documented process for substituting a selected establishment that is closed, inaccessible, duplicated, misclassified, or otherwise ineligible with another eligible establishment from the same stratum and, where feasible, the same cluster.

**Target population** - Refers to the full set of health establishments falling within categories subject to OHSC inspection, and for which an approved inspection tool exists.

# **PART A**

## **MANDATE**





## **1. OHSC LEGISLATIVE MANDATE**

### **1.1. The Constitution of the Republic of South Africa (Act No. 108 of 1996)**

The Bill of Rights in the South African Constitution underpins the entire health system. Section 27 establishes a universal right to access healthcare services, including reproductive health services and emergency medical treatment. The law makes it clear that no person may be denied emergency medical treatment.

The Constitution requires the state to take reasonable legislative and other measures, within available resources, to achieve the progressive realisation of access to healthcare. Section 28 of the South African Constitution provides an important benchmark for the protection of children in South Africa, as it enshrines principles derived from international law on children's rights as the highest law of the land. It states that every child has a right to basic health care services.

The regulation of health service quality requires all health establishments to comply with policy priorities and minimum standards of care. In this manner, the regulation of quality contributes directly to the government's progressive realisation of its constitutional obligations. The OHSC carries out its work with due regard to the fundamental rights as contained in the Constitution and other related legislation. Through compliance inspections and related oversight functions, the OHSC contributes to protecting constitutional rights by promoting safe, high-quality, and accountable healthcare services.

### **1.2. The National Health Act, 23 (Act No. 61 of 2003)**

The National Health Act, 2003 (Act No. 61 of 2003) 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 way they were treated at a health establishment. The NHA further obliges Members of the Executive Councils (MECs) to establish procedures for handling complaints within their respective areas of jurisdiction. Complaints provide useful feedback on areas within health establishments that do not comply with prescribed standards or pose a threat to the health and safety of users and healthcare staff.

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 users and ensures broader community participation in healthcare delivery from health facilities to the national level.

The objects of the OHSC in Section 78 of the National Health Amendment Act, 61 of 2003, as amended, are to 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 concerning 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 Section 79 of the NHA, the OHSC must:

- Advise the Minister on matters relating to the norms and standards of the national health system, the review of such norms and standards, or any other matter referred to it by the Minister.
- Inspect and certify compliance by health establishments with prescribed norms and standards, or, where appropriate and necessary, withdraw such certification.
- Investigate complaints relating to breaches of prescribed norms and standards.
- Monitor indicators of risk as an early-warning system for serious breaches of norms and standards and report any breaches to the Minister without delay.
- Identify areas and, where necessary, make recommendations for intervention by a national or provincial department of health, a municipality's health department, or a health establishment, to ensure compliance with prescribed norms and standards.
- Publish any information relating to prescribed norms and standards through the media and, where appropriate, within specific communities.
- Recommend quality assurance and management systems for the national health system to the Minister for approval.
- Keep records of all OHSC activities and

- Advise the Minister on any matter referred to it by the Minister.

In addition, the OHSC may:

- Issue guidelines for health establishments on the implementation of prescribed norms and standards.
- Collect or request any information relating to prescribed norms and standards from health establishments 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 in respect of 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 the Act.

This annual inspection strategy gives practical effect to the OHSC's statutory inspection, certification, monitoring, and reporting functions.

### **1.3. National Health Insurance Act No. 20 of 2023**

To address historical inequities and ensure universal health coverage for all South Africans, the government decided to implement the National Health Insurance (NHI) as part of transforming the health system and granting all citizens access to good-quality health services irrespective of their socio-economic status. The NHI is based on the principles of universal health coverage, the right to access basic health care and social solidarity.

These principles are intertwined with the concept of equity. The NHI, as proposed by the National Department of Health, is not just a new financing mechanism for the health system but also a mechanism for ensuring solidarity in delivering high-quality, accessible services to all South Africans.

The National Health Insurance (NHI) Act 20, 2023, provides for mandatory prepayment of healthcare services in the Republic in pursuance of Section 27 of the Constitution. It establishes an NHI Fund and provides for its powers, functions, and governance structures.

The NHI Act recognises the socio-economic injustices, imbalances, and inequalities of the past, the need to heal the divisions of the past, and the need to establish a society based on democratic values, social justice, and fundamental human rights, and to improve the life expectancy and the quality of life for all citizens.

In relation to the OHSC, the NHI Act provides that “the process of accreditation of healthcare providers will require that health establishments are inspected and certified by the OHSC”. This outlines the crucial role the OHSC plays in implementing the NHI nationwide. It is also important to note that the OHSC's importance lies not only in its role under the NHI.

The OHSC plays a role in the overall responsibility for regulating health establishments and improving healthcare quality in South Africa, both private and public healthcare. While the OHSC's role is integral to the NHI implementation architecture, its inspection and regulatory mandate extend across the broader health system, including both the public and private sectors.

#### **1.4. Norms and Standards Regulations Applicable to Different Categories of Health Establishments, 2018**

The norms and standards regulations applicable to different categories of health establishments were promulgated by the Minister of Health in February 2018. These regulations came into effect in February 2019 and are used to inspect and certify health establishments as compliant.

The purpose of these regulations is to promote and protect the health and safety of users and healthcare personnel. These norms and standards regulations are structured into seven (7) chapters, which are the following:

Chapter 1: covers Definitions, Purpose and Scope of the Regulation. These areas are administrative components of the regulations. Chapters 2 -7 below cover the service delivery aspects, and they are as follows:

- Chapter 2 – User Rights
- Chapter 3 – Clinical Governance and Clinical Care
- Chapter 4 – Clinical Support Services
- Chapter 5 – Facilities and Infrastructure
- Chapter 6 - Governance and Human Resources

- Chapter 7 – General Provisions

The chapter structure of the regulations informs the architecture of inspection tools, evidence requirements, scoring approaches, and reporting of compliance findings.

### **1.5. Procedural Regulation Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, 2016**

The procedural regulations were promulgated by the Minister of Health and published in the Gazette on 13 October 2016 to guide the exercise of powers conferred on the OHSC, the Board, the Chief Executive Officer, the Health Ombud and the Inspectors by the Amendment Act. The regulations elaborate on procedures and processes to be followed by the OHSC.

In the procedural Regulations, Regulation 12(1) requires the Board to approve an annual inspection strategy to guide the Office's inspection activities. Regulation 12(2)(a)(b), provided that the annual inspection strategy must be published on the Office website and include, at least, the following:

An approach to prioritising, scheduling and conducting inspections and Resources for the implementation of the inspection strategy.

These procedural regulations apply to all categories of health establishments within the scope of the NHA and govern, among other matters, inspection notices, additional inspections, entry and search, reporting, certification, enforcement, and appeals. The regulations refer to a notice of inspection to be issued to the establishment. The notice of inspection issued by the OHSC to the person in charge seven days before the inspection, allowing the health establishment to prepare for inspection. Administrative justice provisions for the person in charge of a health establishment are ensured through the annual distribution of the inspection strategy, which indicates the proportion of health establishments to be inspected in a particular year, without naming those establishments.

# **PART B**

## **STRATEGIC FOCUS**





## 2. VISION

Assuring safe and quality health for all.

## 3. MISSION

To monitor and enforce healthcare safety and quality standards in health establishments independently, impartially, fairly, and fearlessly on behalf of healthcare users

## 4. VALUES

The OHSC's value statements, reflected below, state that the OHSC will endeavour to:



## **5. SITUATIONAL ANALYSIS**

### **5.1. External Environment Analysis**

The primary strategic focus for the OHSC is to effectively fulfil its mandate, particularly in compliance inspections, certification, and enforcement, despite serious resource limitations.

The OHSC, as a Public Finance Management Act (PMFA), Schedule 3A public entity, relies heavily on the budget allocations from the National Treasury to carry out all its organisational functions. Over the past years, the OHSC has been operating under extreme budgetary constraints.

Resource constraints directly limit OHSC's ability to expand operations, such as developing inspection tools, increasing inspection coverage, implementing risk-based inspections, and decentralising inspection functions. There were unforeseen environmental factors which affected inspections in some parts of the country, such as extreme weather events. These environmental events in other provinces required the use of high-suspension vehicles to reach HEs because of destroyed road infrastructure, thereby increasing the budget for inspection activities.

In some instances, health establishments were repurposed without alerting the OHSC. The repurposing of HEs without reporting to OHSC affects the classification of the HE and the OHSC inspection plans, as the HE might have been inspected at a different level of care and may need to be reinspected at the new classification level. Similarly, HEs which were closed for whatever reason were not reported to OHSC and were only realised while the inspectors were on the grounds. These unforeseen circumstances further negatively impacted the compliance inspectorate plan and budget.

### **5.2. Internal Environment Analysis**

The OHSC has a clearly defined legal mandate in the quality-assurance environment for public and private healthcare sectors. The OHSC utilises qualified inspectors to conduct compliance inspections in accordance with norms and standards. The OHSC envisaged that the recommendations would improve the quality of health care services. To this end, the OHSC started an alternative virtual verification modality to scale up inspection coverage. The virtual verification process uses virtual platforms

such as Teams and Zoom to verify the presence of previously outstanding items during routine inspections. However, resource constraints in finance and staff shortages hinder the implementation of initiatives to improve inspection coverage and the quality of inspection reports.

The inspection and certification process flow was revised to release reports within shorter timelines than prescribed in the regulations. The Information Technology system's faults and upgrades delay the release of the reports within the required timeframes, and delay access to the system by inspectors and the HE person in charge.

# PART C

## MEASURING COMPLIANCE INSPECTORATE PERFORMANCE



## 6. COMPLIANCE INSPECTORATE PERFORMANCE

### 6.1. Outcomes and Indicators

The indicators and annual targets set out in table 1 below are included in the 2026/27 Annual Performance Plan (APP) of the OHSC's five (5)-year Strategic Plan (2025/26 – 2029/30). The Annual Performance Plan inspection targets for FY 2026/27 were set at 20% for public-sector inspections and 16.3% for the private sector, based on the overall denominator of HEs in the OHSC database. The HEs with an active certificate of compliance are not eligible for inspection until the certificate expires or if triggered by the OHSC early warning system.

Further considerations in selecting HEs for inspection incorporated operational considerations affecting accessibility and travel. The proportion of HEs selected each year is determined by the total number of HEs, the 4 to 5-year period during which each is inspected at least once and the available capacity of OHSC. The denominators for both the public and private sectors are extracted from the OHSC-verified registers and are limited to those HEs categories for which inspection tools are available.

The total number of public HEs planned for inspection over a five-year strategic plan is 3,805. The target for additional inspections can only be measured after the routine inspections are conducted and their outcomes determined. The OHSC does not predetermine the inspection outcomes until the final report is released. The numbers of the APP indicators in table 1 are derived from the NDoH master facility list for public and the OHSC register for general practices in private sector.

**Table 1: Compliance Inspectorate Outcome and Annual Performance Indicators**

| Outcome                                                | Outputs                                                                                           | Output indicators                                                                                                                                                                                                                          | Annual target FY 2026/27 |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Improved inspection coverage of health establishments. | Public health establishments are inspected for compliance with the norms and standards.           | Percentage of public health establishments inspected for compliance with the norms and standards                                                                                                                                           | 20%<br>(761/3805)        |
|                                                        | Private health establishments are inspected for compliance with the norms and standards.          | Percentage of private health establishments inspected for compliance with the norms and standards                                                                                                                                          | 16.3%<br>(210/1290)      |
|                                                        | Additional inspections are conducted in health establishments where non-compliance was identified | Percentage of additional inspection (re-inspection) conducted in public and private health establishments (graded Excellent, Good or Satisfactory) that have completed the regulated reporting period where non-compliance was identified. | 70%                      |
|                                                        | Regulated annual inspection reports published                                                     | Number of annual inspection reports that set out the compliance status of all health establishments and summarise the number and nature of the compliance notices issued.                                                                  | 1                        |

## 6.2. Indicators and Quarterly Targets for FY 2026/27

Table 2 below reflects the quarterly targets for routine inspections (private and public sector), reinspection coverage, and periodic reporting.

**Table 2: Compliance Inspectorate Indicators' Quarterly Targets**

| Indicator                                                                                                                                                                                                                                   | Reporting Period | Annual Target       | Quarterly Targets |                  |                   |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------|-------------------|------------------|-------------------|-------------------|
|                                                                                                                                                                                                                                             |                  |                     | 1 <sup>st</sup>   | 2 <sup>nd</sup>  | 3 <sup>rd</sup>   | 4 <sup>th</sup>   |
| Percentage of public health establishments inspected for compliance with the norms and standards                                                                                                                                            | Quarterly        | 20%<br>(761/3805)   | 5%<br>(190/3805)  | 5%<br>(191/3805) | 5%<br>(190/3805)  | 5%<br>(190/3805)  |
| Percentage of private health establishments inspected for compliance with the norms and standards                                                                                                                                           | Quarterly        | 16.3%<br>(210/1290) | 4%<br>(52/1290)   | 4%<br>(52/1290)  | 4.1%<br>(53/1290) | 4.1%<br>(53/1290) |
| Percentage of additional inspections (re-inspection) conducted in public and private health establishments (graded Excellent, Good or Satisfactory) that have completed the regulated reporting period where non-compliance was identified. | Quarterly        | 70%                 | 70%               | 70%              | 70%               | 70%               |
| Number of annual inspection reports that set out the compliance status of all health establishments and summarise the number and nature of the compliance notices issued.                                                                   | Annually         | 1                   | -                 | -                | 1                 | -                 |



### 6.3. Coverage of Public Health Establishments to be Inspected Per Province, FY 2026/27

Table 3 presents the distribution of health establishments across provinces. The inspection targets for public health establishments were derived from the OHSC Health Establishment Register, which lists 3,875 health establishments (see Table 3). However, due to budgetary and human resource constraints, a total of 3,805 inspections is planned over the next five years. Of these, 761 inspections are targeted for the 2026/2027 financial year. Only HEs for which the OHSC has inspection tools developed for the relevant categories were selected.

Provinces with the highest number of HEs are Eastern Cape (EC), KwaZulu-Natal (KZN), and Limpopo; therefore, they have more planned inspections. The HEs, which have already been inspected over the years, are not eligible for inspection in FY 2026/27 until after four years.

In the 2026/27 FY, the selection of eligible and outstanding HEs is made using the annual APP targets of 20% for public and 16.3% for private. Further details are provided in the methodology and inspection process in section D below.

**Table 3: Distribution of Public Health Establishments Across the Provinces**

| Public Sector<br>FY 2026/27  | Eastern<br>Cape | Free<br>State | Gauteng | KwaZulu<br>-Natal | Limpopo | Mpum<br>alanga | North<br>West | Northern<br>Cape | Western<br>Cape | TOTAL |
|------------------------------|-----------------|---------------|---------|-------------------|---------|----------------|---------------|------------------|-----------------|-------|
| Selected<br>Number<br>of HEs | 173             | 65            | 43      | 182               | 101     | 50             | 53            | 47               | 47              | 761   |
| Total<br>number of<br>HEs    | 851             | 254           | 402     | 689               | 524     | 326            | 333           | 178              | 318             | 3875  |

### 6.3. Coverage of Private/General Practitioners' Health Establishments FY 2026/27

Table 4 below shows the distribution of targeted inspections of General Practices across the nine (9) provinces in this financial year. The country does not have a comprehensive database for all existing General Practices. The OHSC has embarked on an ongoing registration process to create a comprehensive database of GPs, which will also be used to schedule GP inspections and to provide more detailed information on existing General Practices in the country.

In this FY, inspection targets for private health establishments were derived from the Master Health Facility List for the General Practices (1052) and the Health Establishment Register for private acute hospitals (238) which were all inspected in FY 2024/25, resulting in a total target of 1,290 private sector inspections over the five years. For the 2026/2027 financial year, a total of 210 of the 1,290 inspections are planned in the private sector.

Table 4 below refers only to the planned target for the financial year, without the denominator of total GPs in each province, which, at this stage, remains undetermined.

The current GP inspection allocation is based on the verified GP inspection register from the OHSC GP database available to the OHSC at the time of planning. It must not be interpreted as representing the full national GP population. The register will be progressively strengthened through continued registration and data validation. The distribution was based on the availability of GPs for a specific province in the OHSC register.

**Table 4: Distribution of General Practices Across the Provinces**

| General Practices<br>FY 2026/27 | EC | FS | GP | KZN | LP | MP | NW | NC | WC | TOTAL |
|---------------------------------|----|----|----|-----|----|----|----|----|----|-------|
| Health Establishments           | 21 | 24 | 48 | 34  | 8  | 26 | 12 | 11 | 26 | 210   |

# PART D

TYPE OF INSPECTIONS,  
PROCESSES AND  
METHODOLOGY



## **7. INSPECTION PROCESSES AND METHODOLOGY**

### **7.1. Annual Returns**

In line with the provisions of the Procedural Regulations pertaining to the functioning of the OHSC and Handling of Complaints by the Ombud, all health establishments are required to provide information relating to norms and standards regulations in terms of section 79(2)(b) of the Act by 31 March of each year. The submission of such information, referred to as an Annual Return (AR), enables the OHSC to collect information from health establishments. The Annual Returns inform the OHSC's database of health establishments, which supports planning of compliance inspections, and recognises key contextual trends, commonalities, and discrepancies in available resources across different types of health establishments.

In this regard, information collected through Annual Return submissions is an important component that enables a better understanding of the operational context in which various health establishments operate. In addition, the Annual Returns information, together with other data collected within the OHSC, assists the inspection planning process in profiling health establishments to understand their previous performance with respect to the regulated norms and standards. The Annual Returns submissions are used for various operational modalities, including maintaining the OHSC database, validating the annual inspection frame, confirming the operational status and category of establishments, identifying service changes, and supporting pre-inspection risk profiling and planning.

### **7.2. Selection of Health Establishments**

For the 2026/27 financial year, the OHSC will apply a multi-stage inspection selection methodology to identify health establishments for routine, additional inspection (re-inspection), and risk-based inspection. The approved APP targets will first be distributed across all provinces, including the public and private sectors.

Within each province, eligible health establishments that have never been inspected for compliance with regulated norms and standards, or that do not have an active compliance certificate, will be grouped into geographical clusters. Considering district boundaries, facility proximity, care category, and travel feasibility. The Clusters will

then be selected for inspection within available resources while maintaining a reasonable geographic spread and improving inspection coverage.

The methodology is intended to support the equitable and efficient deployment of inspection resources while advancing the statutory obligation to inspect health establishments for compliance with prescribed norms and standards as enshrined in the National Health Act, sec 79(1)(b), as amended. The OHSC will reintroduce and exercise its mandate contemplated in the National Health Act, 61 of 2003, as amended, and the Procedural Regulations 13(4) to conduct unannounced inspections where there are potential risks to patients' safety and the quality of healthcare. Among the selected HEs, some inspections will be unannounced, without prior notification to health establishments. This should further solidify the OHSC's regulatory functions for compliance with norms and standards and strengthen consistent safety and quality standards.

The target population for routine inspection comprises all health establishments falling within categories for which the OHSC has developed inspection tools. The sampling frame for annual selection will be derived from the OHSC master health establishment register, annual returns submitted by health establishments, prior inspection records, and other verified internal datasets. The frame will be updated before finalisation of the annual inspection schedule to remove duplicate, closed, misclassified, or otherwise ineligible establishments.

The primary inspection unit is an individual health establishment. However, for annual planning purposes, establishments may be grouped into geographical clusters at the district, sub-district, or locality level to improve operational efficiency and reduce travel time and cost. This clustering will support system-level analysis of common compliance challenges affecting establishments operating within the same service environment and allow OHSC to provide feedback on inspection performance.

For the General Practice inspections, the OHSC will also apply the geographically clustered approach described above and use the available OHSC-verified GP register. This approach is adopted to improve route efficiencies and reduce inspection costs where practices are widely distributed, while the national GP database is still being

strengthened. Selection will therefore be made from the currently available and verified OHSC GP inspection register.

Additional inspections (re-inspections) will be selected from health establishments previously inspected by the OHSC where non-compliance was identified, and the Act, Procedural Regulations, APP requirements, Compliance Notices, or risk considerations require follow-up verification. In scheduling re-inspections, the OHSC will use similar geographic clustering and align them with the routine inspection schedule. The eligible HEs would have been those who achieved non-compliant status with a satisfactory, good, or excellent grade.

Risk-based inspections will be selected outside the routine annual inspection schedule. They may be initiated at any time based on Early Warning System alerts, complaints, Ombud findings, media reports, serious incidents, or other verified indicators of breach of norms and standards. Risk-based inspections are therefore trigger-based and not dependent on cluster inclusion.

The OHSC recognises that the described methodology is primarily designed for regulatory planning, service coverage, and the efficient deployment of inspection capacity, rather than for statistical estimation of the national compliance rate. The methodology accordingly balances legality, fairness, operational feasibility, and risk responsiveness.

Where an establishment selected for inspection is found to be closed, inaccessible, duplicated on the register, incorrectly classified, or otherwise ineligible, it will be replaced by the next eligible establishment within the same province. The category, and, where feasible, the same geographical cluster, so that annual targets can be protected without materially distorting the inspection plan.

This selection methodology supports the OHSC's broader role in strengthening compliance oversight, improving inspection coverage within constrained resources, and supporting the implementation of National Health Insurance through a credible, transparent, and risk-responsive inspection programme.



## **8. TYPES OF INSPECTIONS**

### **8.1. Routine Inspections**

According to the National Health Act 61 of 2003, as amended, every health establishment must be inspected. These inspections are conducted at health establishments to determine their compliance with regulatory norms and standards. Routine inspections are planned inspections conducted to assess compliance with prescribed norms and standards within the regulated inspection cycle, using announced or unannounced modalities as permitted by law.

### **8.2. Additional Inspections**

Additional inspections are conducted to monitor breaches identified during routine inspections and ensure that they have been remedied. In terms of the Regulations, an inspector may, at any time, subject to section 82(1) of the Act, conduct an additional inspection if he or she has reasonable grounds to believe that: Such an inspection is needed to establish whether non-compliance has been remedied within the health establishment:

- a) The health establishment is in contravention of the Act or any relevant regulations.
- b) There are serious breaches of norms and standards based on the indicators of risk, or
- c) The Ombud's findings demonstrate that continued exposure to the healthcare services provided by health establishments may pose a severe risk to users or healthcare personnel.

### **8.3. Risk-Based Inspections**

Risk-based inspections are driven by the Early Warning System's surveillance mechanism. These inspections are initiated in response to various triggers, including, but not limited to; alerts from the Early Warning System, complaints lodged by members of the public, reports from mainstream and social media regarding breaches of norms and standards, contraventions of the Act, and findings from the Health Ombud in accordance with procedural regulation (5)(2)(b)(c) and (d).

#### **8.4. Unannounced Inspections**

An unannounced inspection is a regulatory inspection conducted by the Office of Health Standards Compliance without prior notification to a health establishment. Unannounced inspections may be risk-based, complaint-driven, or random, and may also be used to verify previously identified non-compliance. All inspections are conducted in accordance with applicable legislation, regulatory frameworks, and approved inspection methodologies contemplated in the National Health Act, 61 of 2003, as amended and the procedural regulations 13(4)

Such inspections are undertaken to obtain an objective and accurate representation of the quality of care, patient safety practices, and operational performance of the establishment, free from preparatory influence.

#### **8.5. Inspection Process**

The following processes are undertaken when planning, conducting and reporting for inspections:

- Distribution and circulation of the inspection schedule
- Notice of Inspection - sent to health establishments to be inspected
- Conducting the inspection
- Team validations
- Post inspection peer review
- Internal and external quality controls
- Issuing of final inspection reports and
- Publishing of reports.

The processes utilised for the collection of data during inspections are the following:

- Observation of clinical areas for cleanliness and the availability of information in the local language for patients to read.

- Document review for the availability of guidelines and Standard Operating Procedures.
- Analysis of patients' records for accuracy and proper documentation of clinical care.
- Staff interviews to determine their knowledge of the existing guidelines.
- Collection of inspection evidence (where necessary)
- Virtual verification of re-inspections

The OHSC will utilise a smart approach to scale up inspection coverage, leveraging digital technology alongside traditional onsite inspections. Smart inspection modalities are intended to supplement, streamline, and better target onsite inspection activity; they do not eliminate the need for physical verification where direct observation, record inspection, or contextual assessment is required.

The approach will focus on reviewing documents before the on-site inspection. This will allow the inspector to focus on other inspection methodologies such as observation, interviews, and records review. The approach anticipates reduced inspection time for one health establishment and the simultaneous inspection of more health establishments. The approach will require:

- Submission and/or uploading of all documents for evaluation by the inspector.
- The inspector will identify and communicate the required documents for submission to the person in charge of the health establishment a week before the inspection visit.
- The person in charge of the health establishment must upload the requested documents by the due date.
- Virtual verification via Teams or Zoom, along with video calls to observe specified measures, will also form part of the approach.

Verbal consent must be obtained from the users and healthcare personnel who will be interviewed. Relevant information, documents, records, objects, and materials produced should be reviewed and analysed for inspection purposes to determine compliance with regulation 14(4).

## **8.6. Estimated Duration for Inspections of Various Categories of Health Establishments.**

The inspection team will spend varying amounts of time at each HE, depending on its size and level of care. The following is provided as a guideline for the time required at HE's:

- Clinic – one full day
- Community Health Centre – one full day
- Hospitals – two (2) to five (5) days, depending on the category of the health establishment.
- General Practice – one full day.

These durations are indicative planning norms and may be adjusted depending on the size, complexity, service package, prior risk profile, and extent of pre-submitted documentation available for review.

## **8.7. Distribution and Circulation of the Inspection Allocation**

The Director: Compliance Inspectorate will schedule inspections and circulate the schedule to inspection team leaders and other relevant stakeholders.

## **8.8. The Pre-Inspection Planning**

The inspectorate team leaders will:

- a) Arrange the pre-inspection planning meeting.
- b) Delegate the responsible inspector to assist with inspection planning.
- c) Allocate tasks to team members to fulfil the pre-inspection planning.
- d) Analyse the annual returns from health establishments.
- e) Check prior inspection reports, enforcement history, and compliance notice status.
- f) Verify whether selected establishments remain active and correctly classified before field deployment.
- g) Monitor media alerts and complaints against the relevant health establishment.

- h) Verify through the early warning system to identify areas of risk related to the health establishment to be inspected, as well as the area.
- i) Identify the terrain in the areas to be inspected, note the distances to be travelled and identify the suitable mode of transport.
- j) Assign functional areas to be inspected to each inspector and
- k) Allocate the Admin Officer to prepare all assessment tools in order of functional areas, using the relevant checklists, and give them to the respective inspectors.

### **8.9. Notice of Inspection**

- a) An inspector will, at any time, before commencing with an inspection contemplated in section 82 of the Act, issue a notice of inspection to the health establishment. The notice of inspection must be issued at least seven working days before the scheduled inspection date.
- b) The notice of inspection referred to in sub-regulation (1) will be signed by the Chief Executive Officer or her delegate.
- c) In terms of regulation 13(4) of the Procedural Regulations Pertaining to the Functioning of the Office of Health Standards Compliance and Handling of Complaints by the Ombud, the OHSC may, if it has reasonable grounds to believe that compliance with the notification requirements referred to in regulation (1) may jeopardise user safety or quality of care, conduct an unannounced inspection of a health establishment.

The notices will include, at a minimum, the following information:

- The purpose of the inspection.
- The date of the inspection.
- The estimated duration.
- The inspection plan referred to in sub-regulation 12(4).
- The number of authorised personnel expected to take part in the inspection.
- The contact details of the inspector primarily responsible for the inspection and
- The responsibilities of the health establishment.

## 8.10. Inspecting a Health Establishment

Upon arrival at the premises in a health establishment, the inspector will:

- a) Identify themselves to the person in charge by presenting:
  - A certificate of appointment as an inspector, issued in terms of section 80(3) of the Act, and
  - A letter of consent referred to in regulation 16(3), or an entry and search warrant issued in terms of section 84(5) of the Act, if applicable.
- b) Explain the purpose of inspection to the managers in relation to the National Health Act as Amended, Act 12 of 2013 and its procedural regulations.
- c) Describe the inspection methodology and process to be followed.
- d) Allow the health establishment to present a facility overview and
- e) The health establishment should ensure that staff are available to assist during the inspections and that a working space is provided.
- f) Upon the inspector completing the identification process with the person in charge, the inspection will commence, and the inspector will present themselves to the relevant functional area for inspection.
- g) Inspectors will introduce themselves in every unit and inform the unit manager about the inspection process.
- h) The inspection process will not interrupt service delivery.
- i) Standardised inspection questionnaires and checklists are used.
- j) The inspector will score using the inspection tool by allocating 1 for compliant and 0 for non-compliant against the prescribed questionnaires and checklists, and Not applicable (N/A) findings are to be made only if the facility does not provide that service, once it has been determined that it is not part of the health establishment's package of services.



## **9. POST-INSPECTION PROCESSES**

### **9.1. Inspection Data Verification and Validation**

The OHSC applies multiple internal quality-control stages to strengthen the reliability, consistency, and defensibility of inspection findings before reports are issued. The internal quality control processes for inspection findings include onsite validation (done by the Team leader), Pre-Preliminary Reviews (Inter-Team), and Pre-Final Reviews (Inter-Team).

### **9.2. Teams Inspection Findings Validation**

The team leader and inspectors verify the submitted inspection findings to ensure the accuracy of the data and the quality of the reports.

### **9.3. Post-Inspection Review (Preliminary Review)**

The Compliance Inspectorate Unit conducts a Pre-Preliminary Review (PPR) to ensure quality controls are in place after inspections.

- Inspection findings undergo internal peer review before the preliminary report is issued to health establishments.
- Peer reviews are conducted within 3 days of an inspection, in accordance with the inspection and certification process flow.
- These measures are employed to maintain standards, improve performance, and ensure the credibility of the inspection findings.

### **9.4. Final Review of Inspection Reports (Pre-Final Review)**

Final reports undergo internal Pre-Final Reviews (PFR), which include a final team leader assessment of Non-Negotiable Measures before the final report is released.

### **9.5. Issuing of Individual Health Establishment Reports.**

The preliminary reports will be issued to the person in charge of a health establishment in writing within twenty working days of post-inspection.

The preliminary reports will:

- Identify the fundamental areas of non-compliance with norms and standards.
- Set out the consequences of non-compliance as contemplated in section 82A (2) and (4) of the Act and
- Set out the steps required to achieve compliance and the periods for corrective action.

The inspector will give the person in charge no more than 20 working days to respond in writing to the preliminary findings. The inspector shall consider the response and issue a final report to the person in charge within 20 days of receipt. After issuing a final report contemplated in sub-regulation 8, the inspector may recommend to the Certification and Enforcement Unit for the issuing of a compliance certificate to the health establishment, in terms of regulation 18(2); or (b) will issue a compliance notice to the health establishment, in terms of section 82A (1) of the Act, if any norms and standards have not been complied with.

## **9.6. Publishing of Reports**

The OHSC is required to publish the following reports:

- a) A list of inspections conducted with the names and locations of the health establishments every six months (bi-annual report).
- b) On an annual basis, produce the Annual Inspection Report for publication on the OHSC public website and any other appropriate publication platform. This inspection report:
  - Sets out the compliance status of all health establishments and
  - Summarises the number and nature of the compliance notices issued.

## 10. COST OF IMPLEMENTING THE INSPECTION STRATEGY

Table 5 below presents the projected budget allocation for the Compliance Inspectorate Unit. The financial projection below outlines the allocation of funds across line items to enable the compliance inspectorate unit to fulfil its mandate.

If the allocated budget for FY 2026/27 remains unchanged from the previous financial year, particularly for goods and services line items. This will continue to hinder efforts to expand inspection coverage and to conduct the GP inspections scheduled this year. This budgetary allocation challenge calls for the Office to explore alternative funding sources and more efficient inspection methods.

The inspection targets were set in line with the National Treasury's Medium-Term Expenditure Framework (MTEF) and the allocated budget. The inspection targets may be revised to align with available financial resources, as needed. The Office will pilot Emergency Medical Services (EMS) tools and commence inspections in this FY, which will require additional resources.

**Table 5: Operation Costs for Compliance Inspectorate Unit.**

### COMPLIANCE INSPECTORATE

| Economic classification               | Medium-term estimates       |                   |                   |                   |                   |
|---------------------------------------|-----------------------------|-------------------|-------------------|-------------------|-------------------|
|                                       | Audited outcomes<br>2024/25 | 2025/26           | 2026/27           | 2027/28           | 2028/29           |
| <b>CURRENT PAYMENTS</b>               | 64,291,934                  | 66,748,540        | 65,984,624        | 69,158,216        | 71,531,918        |
| Compensation of employees             | 45,745,645                  | 49,823,542        | 51,842,120        | 54,699,099        | 57,784,705        |
| Goods and services of which:          | 18,546,289                  | 16,924,997        | 14,142,505        | 14,459,118        | 13,747,212        |
| Travel, subsistence and accommodation | 18,525,799                  | 16,894,997        | 14,111,263        | 14,426,514        | 13,713,144        |
| Inventory and consumables             | 18,490                      | 30,000            | 31,242            | 32,604            | 34,068            |
| <b>TOTAL</b>                          | <b>64,291,934</b>           | <b>66,748,540</b> | <b>65,984,624</b> | <b>69,158,216</b> | <b>71,531,918</b> |

## 11. CONCLUSION

The OHSC has achieved a significant milestone by inspecting private-sector acute hospitals in the previous financial year and including General Practices. The Emergency Medical Services (EMS) tools are nearing finalisation; however, inspection of the EMS level of care depends on resource availability. These additions of other sectors of healthcare services place a considerable demand on available resources.

The 2026/27 Inspection Strategy adopts a risk-responsive and operationally efficient approach to inspection planning to maximise coverage within resource constraints. Through a combination of routine, additional, and risk-based inspections, supported by improved profiling and the introduction of smart inspection modalities, the OHSC will continue to strengthen regulatory oversight, support the implementation of national quality objectives, including the National Health Insurance, and contribute to a safer and more accountable health system.

The OHSC remains committed to ensuring the consistent delivery of high-quality inspection processes through the strategic allocation of resources, the recruitment and retention of suitably qualified personnel, and the effective utilisation of available tools and technological systems. By conducting risk-based inspections across both public and private health establishments, the OHSC fosters transparency, strengthens accountability, and facilitates the implementation of corrective measures where deficiencies are identified.

Furthermore, sustained collaboration with key stakeholders advances broader quality-improvement efforts, thereby reinforcing the OHSC's mandate to enhance regulatory oversight and promote compliance across the healthcare sector.



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