

**IMPORTANT NOTICE**

The Government Printing Works will not be held responsible for faxed documents not received due to errors on the fax machine or faxes received which are unclear or incomplete. Please be advised that an "OK" slip, received from a fax machine, will not be accepted as proof that documents were received by the GPW for printing. If documents are faxed to the GPW it will be the sender's responsibility to phone and confirm that the documents were received in good order.

Furthermore the Government Printing Works will also not be held responsible for cancellations and amendments which have not been done on original documents received from clients.

**CONTENTS • INHOUD**

No.	Page No.	Gazette No.
<b>GENERAL NOTICE</b>		
<b>Health, Department of</b> <i>General Notice</i>		
44 National Health Amendment Bill, 2011: To be tabled by the Minister of Health in Parliament this year .....	3	33962

---

## GENERAL NOTICE

---

### NOTICE 44 OF 2011 DEPARTMENT OF HEALTH

The Minister of Health intends to table the National Health Amendment Bill, 2011 in Parliament this year, 2011.

Interested persons are invited to submit any substantiated comments or presentations in writing on the proposed bill to the Director-General: Health, Private Bag X828, Pretoria, 0001 within three months from the date of publication of this notice.

The Bill is attached and further copies can be obtained from Ms Hyldia Phasha of the Department of Health Legal Services at:

Office 1814 Civitas Building

Corner Andries and Struben Street, Pretoria

Tel: (012) 395 8492

**REPUBLIC OF SOUTH AFRICA**

**NATIONAL HEALTH AMENDMENT BILL**

-----  
*(As introduced in the National Assembly (proposed section 76); explanatory  
summary of Bill published in Government Gazette No.     of     ) (The English text  
is the official text of the Bill)*  
-----

**(MINISTER OF HEALTH)**

**[BILL — 2011]**

010111ca

**BILL**

**To amend the National Health Act, 2003, so as to define certain expressions and to delete certain obsolete definitions; and to provide for the establishment of the Office of Health Standards Compliance; and to provide for matters connected therewith.**

**BE IT ENACTED** by the Parliament of the Republic of South Africa, as follows:—

**Amendment of section 1 of Act 61 of 2003**

1. Section 1 of the National Health Act, 2003 (hereinafter referred to as "the principal Act"), is hereby amended—

- (a) by the deletion of the definition of **"health officer"**;
- (b) by the insertion after the definition of "hospital" of the following definition:  
  
**" 'inspector' means an inspector appointed in terms of section 81C;"**
- (c) by the deletion of the definition of **"Inspectorate for Health Establishments"**;
- (d) by the insertion after the definition of **"norm"** of the following definition:

**" Office of Health Standards Compliance " means the office established in terms of section 77(1);"; and**

- (e) by the deletion of the definition of **"Office of Standards Compliance"**.

#### **Repeal of section 18 of Act 61 of 2003**

2. Section 18 of the principal Act is hereby repealed.

#### **Amendment of section 36 of Act 61 of 2003**

3. Section 36 of the principal Act is hereby amended by the substitution in subsection (6) for paragraph (a) of the following paragraph:

**"(a) on the [recommendations of] information received from the Office of Health Standards Compliance in terms of section [79(7)(b)] 81A(6);"**

#### **Repeal of section 47 of Act 61 of 2003**

4. Section 47 of the principal Act is hereby repealed.

#### **Substitution of Chapter 10 of Act 61 of 2003**

5. The following Chapter is hereby substituted for Chapter 10 of the principal Act:

**"CHAPTER 10****OFFICE OF HEALTH STANDARDS COMPLIANCE****Establishment of Office of Health Standards Compliance, its objects and Independence**

77. (1) The Office of Health Standards Compliance (in this Chapter referred to as the Office) is hereby established as an organ of state at the national sphere of government and is headed by and under the control of an Executive Director appointed in terms of section 81(1).

(2) The objects of the Office is to—

- (a) ensure that complaints from health care users are investigated properly and dealt with expeditiously through an independent mechanism; and
- (b) facilitate compliance by health care providers, health establishments, health facilities and health workers with the norms and standards for the national health system.

(3) No person may in any way interfere with, hinder or obstruct any member of the Office in the performance of his or her functions.

(4) Any person who contravenes or fails to comply with subsection (4) is guilty of an offence.

(5) All organs of state must accord such assistance as may be reasonable required for the effectiveness of the Office in the performance of its functions.

**Functions of Office**

**78. (1) The Office must—**

- (a) advise the Minister on the development of norms and standards for the national health system and the review of such norms and standards;**
- (b) certify health establishments as compliant with prescribed norms and standards;**
- (c) ensure compliance with prescribed norms and standards by health establishments;**
- (d) investigate complaints relating to the health system;**
- (e) monitor indicators of risk as an early warning system relating to serious breaches of standards; and**
- (f) exercise and perform other functions and powers conferred upon it by this Act.**

**(2) The Minister exercises final responsibility over the Office.**

**(3) To enable the Minister to exercise his or her final responsibility in terms of subsection (2), the Executive Director of the Office must, at the request of the Minister—**

- (a) furnish him or her with information or a report with regard to any case, matter or subject dealt with by the Executive Director, an inspector or**

any other employee of the Office in the performance of his or her functions; and

- (b) provide him or her with reasons for any decision taken by the Executive Director, an inspector or any other employee of the Office in the performance of his or her functions.

### **Funds of Office**

79. The Office is funded by—

- (a) money appropriated by Parliament for that purpose;
- (b) fees for services rendered by the Office; and
- (c) donations or contributions received by the Office, with the prior approval of the Minister.

### **Accountability and reporting**

80. (1) The Executive Director must, subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999)—

- (a) cause the necessary accounting and other records to be kept;
- (b) prepare and submit to the Minister an annual report for approval in the form prescribed by the Minister within five months after the end of the financial year.



- (2) The annual report referred to in subsection (1) must include—
- (a) audited annual financial statements by the Auditor-General;
  - (b) the Auditor-General's report; and
  - (c) a detailed report on the activities of the Office undertaken during the year to which the audit relates.

(3) The Minister must table in Parliament a copy of the annual report, financial statements and the audit report on those statements within one month after receipt thereof if Parliament is in session, or if Parliament is then not in session, within one month after the commencement of its next ensuing session.

(4) The Executive Director must publish the annual report, financial statements and the audit report on those statements.

### Appointment of Executive Director

81. (1) The Minister must, subject to the laws governing the public service, appoint a suitably qualified person as an Executive Director.

(2) The Executive Director must—

- (a) be fit and proper person who is a South African Citizen;

(b) hold office for an agreed term not exceeding five years, but which is renewable for one additional term not exceeding five years.

(3) The Minister may remove the Executive Director from office on account of—

(a) misconduct;

(b) ill health; or

(c) inability to perform the duties and functions of that office effectively.

(4) When the Executive Director is absent or otherwise unable to perform the duties and functions of office, or during a vacancy in the office of Executive Director, the Minister may designate another Office employee to act as Executive Director.

(5) No person may be designated as acting Executive Director for a period longer than 90 days at a time.

### Functions of Executive Director

81A. (1) The Executive Director—

(a) is responsible for the exercise of powers and performance of functions of the Office;

(b) is the head and accounting officer of the Office;

- (c) must, subject to the laws governing public service, appoint suitable qualified persons to the employ of the Office in accordance with an organisational structure approved by the Minister;
- (d) takes all decisions in the exercise of powers and performance of functions of the Office; and
- (e) performs any function and exercises any power assigned to the Office in terms of this Act or the Public Finance Management Act, 1999 (Act No. 1 of 1999).

(2) The structure contemplated in subsection (1)(c) must differentiate between employees who are to be appointed and designated as inspectors and ombudsperson in terms of this Act and other employees who are to be appointed to perform other functions in the Office.

(3) As head of the Office, the Executive Director is responsible in particular for—

- (a) the formation and development of an efficient administration;
- (b) the organisation and control of staff;
- (c) the maintenance of discipline; and
- (d) the effective deployment and utilisation of staff to achieve maximum operational results.

(4) As accounting officer, the Executive Director is responsible for—

- (a) the administration and management of the budget of the Office; and
- (b) proper and diligent implementation of the Public Finance Management Act, 1999.

(5) The Executive Director must, in order to achieve the objects of the Office, establish competences and capabilities in its operations, which include but are not limited to—

(a) an Inspectorate; and

(b) an Ombudsperson.

(6) The Office must—

(a) develop and recommend norms and standards for the national health system to the Minister for approval;

(b) develop and recommend quality assurance and management systems for the national health system to the Minister for approval as are necessary to adequately identify and address—

(i) levels and categories of health services in relation to categories of health establishments;

(ii) areas where urgent intervention by a national or provincial department of health is required in order to meet prescribed norms and standards;

(iii) fraud and corruption or abuse of the health system insofar as it affects compliance with prescribed norms and standards;

(c) develop and recommend guidelines on the implementation of prescribed norms and standards for use by health care providers, health establishments, health facilities and health workers;

(d) publish information relating to prescribed norms and standards through media and, where appropriate, to specific communities;

- (e) maintain of records relating to prescribed norms and standards;
- (f) promote the effectiveness and sustainability of the national health system;
- (g) assess information sent by health establishments for purposes of monitoring to determine compliance with prescribed norms and standards;
- (h) objectively measure and evaluate quality and health outcomes regarding specific health establishments and health care providers and categories or groups of health establishments and health care providers;
- (i) empower health care funders and users to recognize and evaluate health establishments with regard to quality and other standards and promotes the transparency of such standards to the general public;
- (j) certify health care providers, health facilities and health establishments in accordance with prescribed norms and standards;
- (k) monitor and evaluate activities and processes designed for the purpose of quality management and assurance in health establishments;
- (l) create incentives for health establishments to participate in quality improvement programmes;
- (m) conduct inspections of health establishments, health facilities, health care providers or health agencies that have applied for the certificate of compliance in terms of this Act or if there is reason to believe that

serious violations of the provisions of this Act or non-compliance with prescribed norms and standards; and

(n) keep a register and record of all inspections conducted by it.

(7) The Ombudsperson must, on receipt of complaint or on its own initiative, investigate and deal with any complaint relating to alleged—

(a) abuse or unjustifiable exercise of power or unfair, discourteous or other improper conduct or undue delay by any person performing a function in the health system; or

(b) act or omission by a person in charge of or employed by a health establishment, health facility or health agency or providing a health service.

(8) In conducting an investigation in terms of subsection (7), the Ombudsperson may—

(a) be assisted by an inspector;

(b) direct any person to submit an affidavit or affirmed declaration or to appear before him or her to give evidence or produce any document in his or her possession or under his or her control which has a bearing on the matter being investigated, and may examine such person;

(c) request an explanation from any person whom he or she reasonably suspects of having information which has a bearing on a matter being or to be investigated;

(d) require any person appearing as a witness before him or her under subsection (10) to give evidence on oath or after having made an affirmation.

(9) A direction referred to in subsection (8)(b) may be by way of a subpoena containing particulars of the matter in connection with which the person subpoenaed is required to appear before the ombudsperson and served on the person subpoenaed either by a registered letter sent through the post or by delivery by a person authorised thereto by the ombudsperson.

(10) If it appears to the ombudsperson that any person is being implicated in the matter being investigated, the ombudsperson shall afford such person an opportunity to be heard in connection therewith by way of the giving of evidence, and such person shall be entitled, through the ombudsperson, to question other witnesses, determined by the ombudsperson, who have appeared before the ombudsperson in terms of this section.

(11) After each investigation contemplated in subsection (7) the ombudsperson shall submit his or her report together with recommendation to the Executive Director for appropriate action.

(12) In considering or taking appropriate action as contemplated in subsection (11) the Executive Director may request the assistance of the South African Police Services in a province if the complaint relates to that particular province.

**Delegation of powers and assignment of duties**

**81B. (1) The Executive Director may—**

**(a) delegate to an employee of the Office any of his or her powers in terms of this Act; or**

**(b) assign to an Office employee any of his or her duties in terms of this Act.**

**(2) The delegation or assignment under subsection (1)**

**(a) must be in writing;**

**(b) may be subject to such terms and conditions the Executive Director may determine or impose;**

**(c) may at any time be amended or revoked by the Executive Director; and**

**(d) does not divest the Executive Director of the responsibility concerning the exercise of the power or the performance of the duty.**

**(3) This section applies only to the Executive Director's duties, powers and responsibilities contained in this Act.**

**Inspectors and other officers**

**81C. The Executive Director must appoint any suitably qualified person with appropriate expertise and skill as inspector to ensure compliance with norms and standards prescribed in terms of this Act.**



**Routine inspections**

**82. (1) [A health officer] An inspector may enter any premises, excluding a private dwelling, at any reasonable time and—**

- (a) inspect such premises in order to ensure compliance with this Act;**
- (b) question any person who he or she believes may have information relevant to the inspection;**
- (c) require the person in charge of such premises to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document that such person is required to maintain in terms of any law; and**
- (d) take samples of any substance that is relevant to the inspection.**

**(2) [A health officer] An inspector may be accompanied by an interpreter and any other person reasonably required to assist him or her in conducting the inspection.**

**(3) [A health officer] An inspector may issue a compliance notice to the person in charge of the premises if a provision of this Act has not been complied with.**

**(4) A compliance notice remains in force until the relevant provision of the Act has been complied with and the [health officer] inspector has issued a compliance certificate in respect of that notice.**

**(5) [A health officer] An inspector who removes any item other than that contemplated in subsection (1)(d) must—**

- (a) issue a receipt for it to the person in charge of the premises; and**

- (b) subject to the Criminal Procedure Act, 1977 (Act No. 51 of 1977), return it as soon as practicable after achieving the purpose for which it was removed.

### **Environmental health investigations**

83. (1) If [a health officer] an inspector has reasonable grounds to believe that any condition exists which—

- (a) constitutes a violation of the right contained in section 24 (a) of the Constitution;
- (b) constitutes pollution detrimental to health;
- (c) is likely to cause a health nuisance; or
- (d) constitutes a health nuisance,

the [health officer] inspector must investigate such condition.

(2) If the investigation reveals that a condition contemplated in subsection (1) exists, the [health officer] inspector must endeavour to determine the identity of the person responsible for such condition.

(3) The [health officer] inspector must issue a compliance notice to the person determined to be responsible for any condition contemplated in subsection (1) to take appropriate corrective action in order to minimise, remove or rectify such condition.

(4) Any person aggrieved by a determination or instruction in terms of subsection (2) or (3) may, within a period of 14 days from the date on which he or she became aware of the determination or instruction, lodge an

appeal with the **[head of the relevant provincial department]** Executive Director.

### **Entry and search of premises with warrant**

**84. (1) [A health officer] An inspector** accompanied by a police official may, on the authority of a warrant issued in terms of subsection (5) and subject to section 86, enter any premises specified in the warrant, including a private dwelling, and—

- (a) inspect, photograph, copy, test and examine any document, record, object or material, or cause it to be inspected, photographed, copied, tested and examined;
- (b) seize any document, record, object or material if he or she has reason to suspect that it might be used as evidence in a criminal trial; and
- (c) examine any activity, operation or process carried out on the premises.

**(2) [A health officer] An inspector** who removes anything from the premises being searched must—

- (a) issue a receipt for it to the owner or person in control of the premises; and
- (b) unless it is an item prohibited in terms of this Act, return it as soon as practicable after achieving the purpose for which it was removed.

**(3) Upon the request of [a health officer] an inspector** acting in terms of a warrant issued in terms of subsection (5), the occupant and any other person present on the premises must—

- (a) make available or accessible or deliver to the health officer any document, record, object or material which pertains to an investigation contemplated in subsection (1) and which is in the possession or under the control of the occupant or other person;
- (b) furnish such information as he or she has with regard to the matter under investigation; and
- (c) render such reasonable assistance as the **[health officer] inspector** may require to perform his or her functions in terms of this Act efficiently.

(4) Before questioning any person at the premises in question, the **[health officer] inspector** or police official must advise that person of his or her right to be assisted at the time by an advocate or attorney, and allow that person to exercise that right.

(5) A warrant contemplated in subsection (1) may be issued by a judge or a magistrate—

- (a) in relation to premises on or from which there is reason to believe that a contravention of this Act has been or is being committed; and
- (b) if it appears from information on oath or affirmation that there are reasonable grounds to believe that there is evidence available in or upon such premises of a contravention of this Act.

(6) The warrant may impose restrictions on the powers of the **[health officer] inspector**.

(7) A warrant issued in terms of this section—

- (a) remains in force until—
  - (i) it is executed;

- (ii) it is cancelled by the person who issued it or, if such person is not available, by any person with like authority;
  - (iii) the expiry of one month from the day of its issue; or
  - (iv) the purpose for the issuing of the warrant has lapsed, whichever occurs first; and
- (b) must be executed by day unless the person who issues the warrant authorises the execution thereof by night.

(8) No person is entitled to compensation for any loss or damage arising out of any bona fide action by a police official or [health officer] inspector under this section.

#### **Identification prior to entry, and resistance against entry**

85. (1) [A health officer] An inspector who has obtained a warrant in terms of section 85(5) or the police official accompanying him or her must immediately before entering the premises in question—

- (a) audibly announce that he or she is authorised to enter the premises and demand admission to the premises; and
- (b) notify the person in control of the premises of the purpose of the entry, unless there are reasonable grounds to believe that such announcement or notification might defeat the purpose of the search.

(2) The [health officer] inspector must—

- (a) hand to the person in control of the premises a copy of the warrant or, if such person is not present, affix such a copy to a prominent place on the premises; and

(b) on request of the person in charge of such premises, show his or her certificate of appointment as **[health officer]** inspector to that person.

(3) **[A health officer]** An inspector or police official contemplated in subsection (1) may overcome resistance to the entry and search by using such force as is reasonably required, including the breaking of a door or window of the premises.

(4) Before using force, the **[health officer]** inspector or police official must audibly demand admission and must announce the purpose of the entry, unless there are reasonable grounds to believe that doing so might defeat the purpose of the search.

#### **Entry and search of premises without warrant**

86. **[A health officer]** An inspector accompanied by a police official may without a warrant exercise any power referred to in section 84(1) if—

- (a) the person who is competent to do so consents to such exercise; or
- (b) there are reasonable grounds to believe that a warrant would be issued in terms of section 84(5) and that the delay in obtaining the warrant would defeat the object of the warrant.

#### **Disposal of items seized by **[health officer]** inspector**

87. (1) The **[health officer]** inspector must deliver anything seized in terms of section 84 or 86 without delay to a police official contemplated in section 30 of the Criminal Procedure Act, 1977 (Act No. 51 of

1977), who must deal with and dispose of the seized item in the manner provided for in Chapter 2 of that Act.

(2) When a police official acts in terms of section 30 (a) or (b) of the Criminal Procedure Act, 1977 (Act No. 51 of 1977), in respect of an item contemplated in subsection (1), he or she must do so after consultation with the **[health officer]** inspector.

**Miscellaneous provisions relating to **[health officers,]** inspectors and compliance procedures**

88. For the purposes of this Act, the heads of national and provincial departments, and the head of a health department of a municipality must be regarded as being—

- (a) the owner and occupier of any premises that the national or provincial department or the municipality occupies or uses; and
- (b) the employer of persons in the service of that national or provincial department or municipality if, as an employer, the national or provincial department or municipality—
  - (i) performs any duty imposed upon an employer by or under this Act; or
  - (ii) exercises any power conferred upon an employer by or under this Act.

**Reconsideration of decision by Office and appeal**

**88A. (1) If a person disagrees with a decision made by the Office in respect of a matter regulated by this Act, that person or a person acting on his or her behalf may, within 90 days of his or her gaining knowledge of that decision, lodge a written application to the Office requesting the Office to reconsider its decision in the prescribed manner.**

**(2) If a person disagrees with a reconsidered decision made by the Office in respect of a matter contemplated in subsection (1), that person or a person acting on his or her behalf may, within 90 days of his or her gaining knowledge of that decision, lodge a written appeal with the Minister against that decision, setting out the reasons why the Minister should set aside or vary that decision.**

**(3) The Minister may—**

**(a) upon receipt of the appellant's written appeal and the Office's reasons for the decision, confirm, set aside or vary that action or decision; or**

**(b) appoint an independent tribunal to consider an appeal contemplated in subsection (2) in the prescribed manner and that tribunal may, after consideration of the matter, confirm, set aside or vary that decision.**

**(4) If the Minister has appointed an independent tribunal in terms of subsection (3) all appeals contemplated in subsection (2) must be considered by that tribunal.**

**(5) Notwithstanding subsection (2), the independent tribunal may in the prescribed manner condone any late appeal by an appellant.**



**Offences and penalties**

89. (1) A person is guilty of an offence if he or she—
- (a) obstructs or hinders [a health officer] an inspector who is performing a function under this Act;
  - (b) refuses to provide [a health officer] an inspector with such information as that person is required to provide under this Act;
  - (c) knowingly gives false or misleading information to [a health officer] an inspector;
  - (d) unlawfully prevents the owner of any premises, or a person working for the owner, from entering the premises in order to comply with a requirement of this Act;
  - (e) impersonates [a health officer] an inspector;
  - (f) fails to comply with a compliance notice issued to him or her by [a health officer] an inspector in terms of this Act; or
  - (g) discloses any information, which was acquired in the performance of any function in terms of this Act and which relates to the financial or business affairs of any person, to any other person, except if—
    - (i) the other person requires that information in order to perform any function in terms of this Act;
    - (ii) the disclosure is ordered by a court of law; or
    - (iii) the disclosure is in compliance with the provisions of any law.
- (2) Any person convicted of an offence in terms of subsection (1) or section 77(4) is liable on conviction to a fine or to

imprisonment for a period not exceeding [five] 10 years or to both a fine and such imprisonment”.

**Short title and commencement**

6. This Act is called the National Health Amendment Act, 2011, and takes effect on a date fixed by the President by proclamation in the *Gazette*.

---









Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001  
Publications: Tel: (012) 334-4508, 334-4509, 334-4510  
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504  
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737  
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001  
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510  
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504  
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737  
Kaapstad-tak: Tel: (021) 465-7531