

REPUBLIC OF SOUTH AFRICA

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# NATIONAL HEALTH AMENDMENT BILL

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*(As introduced in the National Assembly (proposed section 76); explanatory summary of  
Bill published in Government Gazette No. 34739 of 8 November 2011)  
(The English text is the official text of the Bill)*

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(MINISTER OF HEALTH)

[B 24—2011]

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

2. 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 recommendation of**] information received from the Office [**of Standards Compliance**] in terms of section [**79(7)(b)**] 82A(5).”

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### Amendment of section 47 of Act 61 of 2003

3. Section 47 of the principal Act is hereby amended by the substitution for subsection (3) of the following subsection:

“(3) The Office [**of Standards Compliance and the Inspectorate for Health Establishments**] must monitor and enforce compliance with the quality requirements and standards contemplated in subsection (1).”

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

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

#### “CHAPTER 10

#### OFFICE OF HEALTH STANDARDS COMPLIANCE, INSPECTIONS AND ENVIRONMENTAL HEALTH INVESTIGATIONS, HEALTH OFFICERS AND INSPECTORS, COMPLAINTS AND APPEAL PROCEDURE

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#### Establishment of Office of Health Standards Compliance

77. (1) The Office of Health Standards Compliance is hereby established as a juristic person.

(2) The Office is funded by—  
(a) money appropriated by Parliament; and  
(b) fees received for services rendered.

(3) The Office is subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999).

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#### Objects of Office

78. The objects of the Office are to protect and promote the health and safety of users of health services by—

(a) monitoring compliance by health establishments with norms and standards prescribed by the Minister in relation to the national health system; and

(b) ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical and expeditious manner.

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#### Functions of Office

79. (1) The Office must—

(a) advise the Minister on matters relating to the determination of norms and standards to be prescribed for the national health system and the review of such norms and standards;

(b) inspect and certify health establishments as compliant or non-compliant with prescribed norms and standards or, where appropriate and necessary, withdraw such certification;

(c) investigate complaints relating to the national health system;

(d) monitor indicators of risk as an early warning system relating to serious breaches of norms and standards and report any breaches to the Minister without delay;

(e) identify areas and make recommendations for intervention by a national or provincial department of health or a health department of a

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- municipality, where it is necessary, to ensure compliance with prescribed norms and standards;
- (f) recommend quality assurance and management systems for the national health system to the Minister for approval;
- (g) keep records of all its activities; and
- (h) advise the Minister on any matter referred to it by the Minister.
- (2) The Office may—
- (a) issue guidelines for the benefit of health establishments on the implementation of prescribed norms and standards;
- (b) publish any information relating to prescribed norms and standards through the media and, where appropriate, to specific communities;
- (c) collect or request any information relating to prescribed norms and standards from health establishments and users;
- (d) liaise with any other regulatory authority and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority in respect of—
- (i) matters of common interest; or
- (ii) a specific complaint or investigation; and
- (e) negotiate cooperative agreements with any regulatory authority in order to—
- (i) coordinate and harmonise the exercise of jurisdiction over health norms and standards; and
- (ii) ensure the consistent application of the principles of this Act.
- (3) The Minister may prescribe different norms and standards for different types of health establishments.

#### **Appointment of Chief Executive Officer**

- 79A.** (1) The Minister must, subject to the laws governing the public service, appoint a fit and proper and suitably qualified South African citizen as the Chief Executive Officer of the Office.
- (2) The Chief Executive Officer holds office for a term of five years and may be reappointed for one additional term of five years.
- (3) (a) The appointment of a person as the Chief Executive Officer is subject to the conclusion of a written performance agreement entered into between that person and the Minister.
- (b) The Minister and the Chief Executive Officer may, in writing and by agreement, amend the performance agreement.
- (4) The Minister may remove the Chief Executive Officer from office on account of—
- (a) serious misconduct;
- (b) ill health; or
- (c) inability to perform the functions of the Office effectively.
- (5) If the Chief Executive Officer is unable to perform the functions of the Office, or during a vacancy in the office of Chief Executive Officer, the Minister may designate another employee of the Office to act as Chief Executive Officer.
- (6) No person may be designated as acting Chief Executive Officer for longer than 90 days at a time.
- (7) The Chief Executive Officer is entitled to the pension and retirement benefits calculated on the same basis as those of a head of a department in the public service.

#### **Functions of Chief Executive Officer**

- 79B.** (1) The Chief Executive Officer—
- (a) is the head and accounting officer of the Office;
- (b) is responsible for the proper and diligent implementation of the Public Finance Management Act, 1999 (Act No. 1 of 1999); and
- (c) must appoint suitably qualified persons as employees of the Office in accordance with an organisational structure approved by the Minister.
- (2) As head of the Office, the Chief Executive Officer is responsible 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.

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(3) The Chief Executive Officer may enter into contracts with any person or organisation or appoint expert or technical committees to assist the Office in the performance of its functions, including the conducting of inspections.

#### **Delegation of powers and assignment of duties by Chief Executive Officer**

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**79C.** (1) The Chief Executive Officer 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 employee of the Office any of his or her duties in terms of this Act.

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(2) The delegation in terms of subsection (1)—

- (a) must be in writing;
- (b) may be subject to such terms and conditions the Chief Executive Officer may determine or impose;
- (c) may at any time be amended or revoked by the Chief Executive Officer; and
- (d) does not divest the Chief Executive Officer of the responsibility concerning the exercise of the power.

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#### **Accountability of and reporting by Chief Executive Officer**

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**79D.** (1) The Chief Executive Officer 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 by the Minister within five months after the end of the financial year.

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(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 of the activities of the Office undertaken during the year to which the audit relates.

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(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 not in session, within one month after the commencement of its next ensuing session.

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(4) The Chief Executive Officer must, once the annual report, financial statements and audit report have been tabled in Parliament, publish the annual report, financial statements and audit report on those statements in the media.

(5) Notwithstanding subsections (1) and (2), the Chief Executive Officer must, upon request by the Minister—

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- (a) furnish the Minister with information or a report in respect of any case, matter or subject dealt with by the Office; and
- (b) provide the Minister with reasons for any decision taken by the Chief Executive Officer, an inspector or any other employee of the Office.

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#### **Appointment of health officers and inspectors**

**80.** (1) The Minister, relevant member of the Executive Council or mayor of a municipal council may appoint any person in the employ of the national department, province or municipality, as the case may be, as a health officer.

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(2) The Chief Executive Officer must, subject to section 79B(1)(c), appoint any suitably qualified person with appropriate expertise and skill as an inspector.

(3) A health officer or an inspector appointed in terms of this section must be issued with a certificate stating that he or she has been appointed as a health officer or as an inspector in terms of this Act.

(4) When a health officer or an inspector performs any function in terms of this Act, he or she—

- (a) must be in possession of a certificate of appointment issued in terms of subsection (3);
- (b) must show that certificate to any person who is affected by the action of the health officer or inspector in terms of this Act; and
- (c) has the powers of a peace officer, as defined in section 1 of the Criminal Procedure Act, 1977 (Act No. 51 of 1977), and may exercise any of the powers conferred on a peace officer by law.

### Appointment of Ombud

**81.** (1) The Minister must appoint a suitably qualified and experienced person as Ombud.

(2) The Ombud—

- (a) holds office for a non-renewable term of five years;
- (b) is located within the Office; and
- (c) is assisted by persons designated and seconded by the Office with the concurrence of the Ombud.

(3) The Minister, with the concurrence of the Minister of Finance, must determine the remuneration and other terms and conditions of service of the Ombud.

(4) The Ombud may at any time resign by submitting a written notice to the Minister at least 90 days prior to the intended date of vacation of office, unless the Minister allows for a shorter period.

(5) The Minister may terminate the employment of the Ombud on account of serious misconduct, incapacity or incompetence, after affording him or her reasonable opportunity to be heard and subject to applicable legislation.

(6) The Minister must, during a vacancy or when the Ombud is unable to fulfil any of his or her functions, appoint a person on a temporary basis in accordance with subsection (1) to act in the position until a permanent person appointed.

### Functions of Ombud

**81A.** (1) The Ombud may, on receipt of a written or verbal complaint relating to norms and standards, or on his or her own initiative, consider, investigate and dispose of the complaint in a fair, economical and expeditious manner.

(2) A complaint referred to in subsection (1) may involve an act or omission by a person in charge of or employed by a health establishment or any facility or place providing a health service.

(3) In conducting an investigation, the Ombud may, subject to subsection (8)—

- (a) be assisted by any person contemplated in section 81(2)(c);
- (b)
  - (i) obtain an affidavit or a declaration from any person;
  - (ii) direct any person to appear before him or her;
  - (iii) direct any person 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 under consideration or being investigated; and
  - (iv) interrogate 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 under consideration or which is being or to be investigated; and
- (d) require any person appearing as a witness to give evidence under oath or after having made an affirmation.

(4) A direction contemplated in subsection (3)(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 Ombud 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 Ombud.

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

(6) The Ombud may, when considering or investigating a complaint in terms of this section, require the assistance of or refer the complaint to any other authority established in terms of legislation or any other appropriate and suitable body or entity to investigate similar complaints.

(7) The authority, body or entity, as the case may be, contemplated in subsection (6) must provide—

- (a) the Ombud with the assistance required; and
- (b) report to the Ombud on the progress made in relation to complaints referred to it.

(8) No self-incriminating answer given or statement made by any person to the Ombud exercising powers in terms of this Act, is admissible as evidence against that person in criminal proceedings against that person instituted in any court, except in criminal proceedings for perjury or in which that person is tried for an offence contemplated in this Act, and then only to the extent that the answer or statement is relevant to prove the offence charged.

(9) After each investigation, the Ombud must submit a report together with his or her recommendations on appropriate action to the Chief Executive Officer.

(10) The Chief Executive Officer may, subject to subsection (9), request the intervention of the Minister, a member of the executive council responsible for health in a province or a member of the municipal council responsible for health if the complaint relates to a matter falling under the national department or that particular province or municipality, as the case may be.

(11) Where the Chief Executive Officer fails to act in accordance with the findings and recommendations of the Ombud, the Ombud may request the intervention of the Minister.

### **Independence, impartiality and accountability of Ombud**

**81B.** (1) The expenditure connected with the appointment and functions of the Ombud is paid out of funds appropriated by Parliament for that purpose, as part of the budget of the Office.

(2) When dealing with any complaint in terms of this Act, the Ombud, including any person rendering assistance and support to the Ombud—

- (a) is independent and impartial; and
- (b) must perform his or her functions in good faith and without fear, favour, bias or prejudice.

(3) The Minister, Department and Office must afford the Ombud such assistance and support as may be reasonably necessary for the Ombud to perform his or her functions effectively and efficiently.

(4) The Ombud must, within one month after the end of the financial year, prepare a report for the Minister on the affairs and functions of the Ombud during the financial year in question, and submit such report to the Chief Executive Officer for inclusion in the report referred to in section 79D(1).

**Inspections**

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

- (a) inspect such premises or health establishment, as the case may be, in order to ensure compliance with this Act; 5
- (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 or health establishment to produce, for inspection or for the purpose of obtaining copies or extracts thereof or therefrom, any document, including any health record contemplated in section 15, which such person is required to maintain in terms of any law; and 10
- (d) take samples of any substance or photographs relevant to the inspection. 15

(2) A health officer or 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 or an inspector may issue a compliance notice to the person in charge of the premises or health establishment, as the case may be, if any norm and standard or a provision of this Act has not been complied with. 20

(4) A compliance notice remains in force until the relevant provision of the Act has been complied with and the health officer or inspector has issued a compliance certificate in respect of that notice. 25

(5) A health officer or 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 or health establishment, as the case may be; 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. 30

(6) The provisions of section 86A apply with the necessary changes required by the context to inspections conducted in terms of this section.

**Non-compliance with prescribed norms and standards**

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**82A.** (1) An inspector may issue a notice of non-compliance to a person in charge of any health establishment if such establishment does not comply with any prescribed norm and standard.

- (2) The notice contemplated in subsection (1) must set out— 40
  - (a) the health establishment to which the notice applies;
  - (b) any prescribed norm and standard that have not been complied with;
  - (c) details of the nature and extent of non-compliance;
  - (d) any steps that are required to be taken and the period over which such steps must be taken; and
  - (e) the penalties that may be imposed in the event of continued non-compliance. 45

(3) A notice of non-compliance issued in terms of this section remains in force until the Office, on the basis of information furnished by the inspector, issues a certificate of compliance or until it is appealed against and set aside by the tribunal appointed in terms of section 88A(2)(a). 50

(4) If a person in charge of a health establishment to whom a notice of non-compliance has been issued, fails to comply with the notice, the Office may—

- (a) in respect of that non-compliance, impose upon that person or health establishment a fine not exceeding R10 million rand; or 55
- (b) refer the matter to the National Prosecuting Authority for prosecution.

(5) The Chief Executive Officer must inform the Director-General of any non-compliance for the purposes of section 36(6)(a).

### Environmental health investigations

**83.** (1) If a health officer 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 must investigate such condition.

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

(3) The health officer 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 person who appointed a health officer in terms of section 80(1).

(5) Only a health officer who is registered as an environmental health practitioner in terms of the Health Professions Act, 1974 (Act No. 56 of 1974), may exercise any of the powers conferred under this section.

### Entry and search of premises or health establishment with warrant by health officer or inspector

**84.** (1) A health officer or inspector may, where necessary, be accompanied by a police official and may, on the authority of a warrant issued in terms of subsection (5) and subject to sections 85 and 86A, enter any premises, including a private dwelling, or health establishment, as the case may be, specified in the warrant, 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 or health establishment.

(2) A health officer or an inspector who removes anything from the premises or health establishment being searched, as the case may be, must—

- (a) issue a receipt for it to the owner or person in control of the premises or health establishment; 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 or an inspector acting in terms of a warrant issued in terms of subsection (5), the occupant and any other person present on the premises or health establishment, as the case may be, must—

- (a) make available or accessible or deliver to the health officer or inspector any document, record, object or material which pertains to an investigation or inspection 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 or inspection; and
- (c) render such reasonable assistance as the health officer or inspector may require to perform his or her functions efficiently in terms of this Act.

(4) Before questioning any person at the premises or health establishment 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 the premises or health establishment on or from which there is reason to believe an act has been or is being committed in contravention of this Act; and 5
- (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 or health establishment of a contravention of this Act. 10

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

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

- (a) remains in force until— 15
  - (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, 20
 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, a health officer or an inspector under this section. 25

#### **Identification prior to entry, and resistance against entry, by health officer or inspector**

**85.** (1) A health officer or an inspector who has obtained a warrant in terms of section 84(5) or the police official accompanying him or her, must immediately before entering the premises or health establishment in question, as the case may be— 30

- (a) audibly announce that he or she is authorised to enter the premises or health establishment and demand admission to the premises or establishment; and 35
- (b) notify the person in control of the premises or health establishment 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 or inspector, as the case may be, must— 40

- (a) hand to the person in control of the premises or health establishment 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 or health establishment, show his or her certificate of appointment as health officer or inspector to that person. 45

(3) A health officer or an inspector, as the case may be, or a 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 or health establishment. 50

(4) Before using force, the health officer or inspector, as the case may be, 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 or health establishment without warrant by health officer or inspector**

86. A health officer or an inspector may, subject to section 86A, 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.

**Constitutional right to privacy**

- 86A. Any entry upon or search of any premises or health establishment in terms of this Act must be conducted with strict regard to decency and good order, including—
- (a) the right of a person to dignity;
  - (b) the right of a person to freedom and security; and
  - (c) the right of a person to privacy.

**Disposal of items seized by health officer or inspector**

87. A health officer or an inspector may dispose of anything seized in terms of section 84 or 86 in the manner provided for in Chapter 2 of the Criminal Procedure Act, 1977 (Act No. 51 of 1977).

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

88. For the purposes of this Act, the head of a national or provincial department or the head of a health department of a municipality must be regarded as being—
- (a) the owner and occupier of any premises or health establishment 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.

**Appeals against decisions of Office or Ombud**

- 88A. (1) Any person aggrieved by any decision of the Office or any finding and recommendation of the Ombud in relation to a matter regulated by this Act, or a person acting on his or her behalf, may within 30 days of him or her gaining knowledge of that decision, lodge a written appeal with the Minister.
- (2) The Minister must, upon receipt of the appellant's written appeal contemplated in subsection (1)—
- (a) appoint an independent *ad hoc* tribunal in terms of subsection (3);
  - (b) submit the appeal to the tribunal for adjudication in the prescribed manner.
- (3) A tribunal contemplated in subsection (2) must consist of not more than three persons, of whom—
- (a) one must be a person who is a retired judge of a High Court or a retired magistrate, who must be the chairperson; and
  - (b) two must be persons appointed on account of their knowledge of the health care industry.
- (4) A tribunal contemplated in subsection (2)—
- (a) may confirm, set aside or vary the decision of the Office or Ombud; and
  - (b) must notify the parties of its decision.

**Offences and penalties**

**89.** (1) A person is guilty of an offence if he or she—

- (a) obstructs or hinders a health officer or an inspector who is performing a function or any other person rendering assistance or support to a health officer or an inspector under this Act; 5
- (b) refuses to provide a health officer or 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 or an inspector;
- (d) unlawfully prevents the owner of any premises or health establishment, or a person working for the owner, from entering the premises or establishment in order to comply with a requirement of this Act; 10
- (e) impersonates a health officer or an inspector;
- (f) fails to comply with a compliance notice issued to him or her by a health officer or an inspector in terms of this Act; 15
- (g) discloses any information acquired in the performance of any function in terms of this Act which relates to the financial or business affairs of any person, to any other person, except if—
  - (i) such other person requires that information in order to perform any function in terms of this Act; 20
  - (ii) the disclosure is ordered by a court of law; or
  - (iii) the disclosure is in compliance with the provisions of any law; or
- (h) interferes with, hinder or obstructs the Ombud or any other person rendering assistance or support to the Ombud when he or she is performing or exercising a function or power under this Act. 25

(2) Any person convicted of an offence in terms of subsection (1) is liable on conviction to a fine or to imprisonment for a period not exceeding 10 years or to both a fine and such imprisonment.”.

**Amendment of section 90 of Act 61 of 2003** 30

**5.** Section 90 of the principal Act is hereby amended—

- (a) by the substitution in subsection (1) for the words preceding paragraph (a) of the following words:
 

“The Minister, after consultation with the National Health Council or the Office, as the case may be, may make regulations regarding—”; and 35
- (b) by the substitution in subsection (1) for paragraph (b) of the following paragraph:
 

“(b) (i) the fees to be paid to public health establishments for health services rendered; or  
(ii) the fees to be paid to the Office for services rendered;”. 40

**Amendment of Arrangement of Sections of Act 61 of 2003**

**6.** The Arrangement of Sections of the principal Act is hereby amended—

- (a) by the substitution for the heading of Chapter 10 of the following heading:
 

**“[HEALTH OFFICERS AND COMPLIANCE PROCEDURES] OFFICE OF HEALTH STANDARDS COMPLIANCE, INSPECTIONS AND ENVIRONMENTAL HEALTH INVESTIGATIONS, HEALTH OFFICERS AND INSPECTORS, COMPLAINTS AND APPEAL PROCEDURES”**; 45
- (b) by the substitution for item 77 of the following item:
 

**“Establishment of [Inspectorate for Health Establishments] Office of Health Standards Compliance”**; 50
- (c) by the substitution for item 78 of the following item:
 

**“[Office of Standards Compliance] Objects of Office”**;
- (d) by the substitution for item 79 of the following item:
 

**“[Inspections by Office of Standards Compliance] Functions of Office”**; 55

- (e) by the insertion after item 79 of the following items:  
**79A. Appointment of Chief Executive Officer**  
**79B. Functions of Chief Executive Officer**  
**79C. Delegation of powers and assignment of duties by Chief Executive Officer** 5  
**79D. Accountability of and reporting by Chief Executive Officer**;
- (f) by the substitution for item 80 of the following item:  
**“Appointment of health officers and inspectors”**;
- (g) by the substitution for item 81 of the following item:  
**“[Duty of health officers] Appointment of Ombud”**; 10
- (h) by the insertion after item 81 of the following items:  
**“81A. Functions of Ombud**  
**81B. Independence, impartiality and accountability of Ombud”**;
- (i) by the substitution for item 82 of the following item:  
**“[Routine inspection] Inspections”**; 15
- (j) by the insertion after item 82 of the following item:  
**“82A. Non-compliance with prescribed norms and standards”**;
- (k) by the substitution for item 84 of the following item:  
**“Entry and search of premises or health establishment with warrant by health officer or inspector”**; 20
- (l) by the substitution for item 85 of the following item:  
**“Identification prior to entry, and resistance against entry, by health officer or inspector”**;
- (m) by the substitution for item 86 of the following item:  
**“Entry and search of premises or health establishment without warrant by health officer or inspector”**; 25
- (n) by the insertion after item 86 of the following item:  
**“86A. Constitutional right to privacy”**;
- (o) by the substitution for item 87 of the following item:  
**“Disposal of items seized by health officer or inspector”**; 30
- (p) by the insertion after item 88 of the following item:  
**“88A. Appeal procedures”**; and
- (q) by the substitution for item 89 of the following item:  
**“Offences and penalties”**.

#### **Amendment of laws** 35

7. With effect from the coming into operation of the provisions relating to the Office of Health Standards Compliance, the Public Finance Management Act, 1999 (Act No. 1 of 1999), is hereby amended by the insertion in Part A of Schedule 3 after the expression “Nelson Mandela Museum, Umtata” of the expression “Office of Health Standards Compliance”. 40

#### **Short title and commencement**

8. 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*.

**MEMORANDUM ON THE OBJECTS OF THE NATIONAL HEALTH  
AMENDMENT BILL, 2011**

**1. BACKGROUND**

- 1.1 The National Health Amendment Bill (the Bill) seeks to amend the National Health Act, 2003 (Act No. 61 of 2003) (the Act), to empower the Minister to establish an independent entity, namely the Office of Health Standards Compliance (the Office).
- 1.2 The role of the Office will be to—
- (a) advise the Minister on the development and implementation of enforceable norms and standards for quality and safety for the entire health system;
  - (b) ensure compliance with the prescribed norms and standards; and
  - (c) deal with complaints relating to the entire health system.

**2. OBJECTS OF BILL**

*Clause 1: Amendment of section 1 of Act*

- 2.1 Clause 1 seeks to amend section 1 of the Act by inserting, substituting or deleting certain definitions consequent to the establishment of the Office.

*Clause 2: Amendment of section 36 of Act*

- 2.2 Clause 2 seeks to amend paragraph (a) of section 36(6) of the Act in order to align the wording and reference consequent to the establishment of the Office.

*Clause 3: Amendment of section 47 of Act*

- 2.3 Clause 3 seeks to amend section 47(3) of the Act in order to delete the reference to the Office of Standards Compliance and the Inspectorate of Health Establishments, which is to be replaced by the Office.

*Clause 4: Substitution of Chapter 10 of Act*

- 2.4 Clause 4 seeks to substitute Chapter 10 of the principal Act in order to provide the following:
- (1) Establishment of Office;
  - (2) Objects of Office;
  - (3) Functions of Office;
  - (4) Appointment of Chief Executive Officer;
  - (5) Functions of Chief Executive Officer;
  - (6) Delegation of powers and assignment of duties by Chief Executive Officer;
  - (7) Accountability of and reporting by Chief Executive Officer;
  - (8) Appointment of health officers and inspectors;
  - (9) Appointment of Ombud;
  - (10) Functions of Ombud;
  - (11) Independence, impartiality and accountability of Ombud;
  - (12) Inspections;
  - (13) Non-compliance with prescribed norms and standards;
  - (14) Environmental health investigations;
  - (15) Entry and search of premises or health establishment with a warrant by health officer or inspector;
  - (16) Identification prior to and resistance against entry by health officer or inspector;
  - (17) Entry and search of premises or health establishment without warrant by health officer or inspector;
  - (18) Constitutional right to privacy;

- (19) Disposal of items seized by health officer or inspector;
- (20) Miscellaneous provisions relating to health officers, inspectors and compliance procedures;
- (21) Appeals against decisions of Office and Ombud; and
- (22) Offences and penalties.

***Clause 5: Amendment of section 90 of Act***

- 2.5 Clause 5 seeks to amend section 90(1) of the principal Act in order to provide for—
- (a) consultation by the Minister with the Office, in addition to the National Health Council, when the Minister makes regulations in terms of the Act; and
  - (b) the Minister to prescribe fees to be paid to the Office for services rendered.

***Clause 6: Amendment of Arrangement of sections of Act***

- 2.6 Clause 6 seeks to amend the arrangement of sections of the Act consequent to the substitution of Chapter 10.

***Clause 7: Amendment of laws***

- 2.7 Clause 7 seeks to amend the Public Finance Management Act, 1999 (Act No. 1 of 1999) (the PFMA), in order to insert the name of the Office in Part A of Schedule 3 to the PFMA, for the PFMA to apply to the Office.

***Clause 8: Short title and commencement***

- 2.8 Clause 8 provides for the name or title of the Act and for the date on which the Act will come into operation.

**3. PERSONS OR BODIES CONSULTED**

The Bill was published on 24 January 2011 for public comments. Comments were received from the following institutions and persons:

NO	COMPANY	PARTICIPANT	CONTACT
1.	BOARD OF HEALTHCARE FUNDERS OF SOUTH AFRICA	DR HUMPRHEY ZOKUFA	(011) 537-0200
2.	SOUTH AFRICAN MEDICAL ASSOCIATION	DR NORMAN MABASA	(012) 481-2000
3.	MEDICAL PROTECTION SOCIETY	DR GRAHAM HOWARTH	(0113) 241-0516 (UK)
4.	LIFE GROUP: HEALTH CARE	ADAM PAYLE	(011) 219-9000
5.	HEALTH: EASTERN CAPE PROVINCE	NOMVANA NKALANE	
6.	HEALTH: WESTERN CAPE PROVINCE	MR E BONZET	(021) 421-1124
7.	HEALTH: MPUMALANGA PROVINCE	CAREEN SWART	(013) 766-3448
8.	HEALTH: NORTH WEST PROVINCE	MR OMR MOKATE	
9.	HEALTH: LIMPOPO PROVINCE	S. L. SIMBA	
10.	HEALTH: GAUTENG PROVINCE	LIZELLE VAN NIEKERK	(012) 358-8689
11.	SOUTH AFRICAN INSTITUTE OF ENVIRONMENTAL HEALTH	S. MUDALY	(031) 8793
12.	HEALTH: DIR: ENVIRONMENTAL HEALTH	MS B MAKHAFOLA	(012) 395-8527
13.	OUR HEALTH SOUTH AFRICA	DR KIM FAURE	082 565 1388
14.	WP BLOOD TRANSFUSIONS SERVICE	DR GRM BELLAIRS	(044) 874-2074
15.	DISCOVERY HEALTH	DR MANDI MZIMBA	(011) 529-5030

NO	COMPANY	PARTICIPANT	CONTACT
16.	OFFICE OF EXECUTIVE MAYOR	ALDERMAN DAN PLATO	(021) 400-1300
17.	NORTONS INC	ANTON ROETS	(011) 666-7560
18.	HEALTH: ENVIRONMENTAL HEALTH	MR R. LOYKISOONLAAL	(012) 395-8781
19.	DLA CLIFFE DEKKER HOFMEYR	MR DE LANGE	(021) 405-6165
20.	THE SOUTH AFRICAN DENTAL ASSOCIATION	MS MARETGA SMIT	(011) 484-5288
21.	CLICKS GROUP LIMITED	MR KNEALE	(021) 460-1911
22.	NATIONAL TREASURY	MR BLECHER	(012) 315-5894
23.	WERKSMANS ATTORNEYS	MR KIRBY	(011) 535-8198
24.	BOOKA CONSULTING CC	ADV. BHUKA	082 062 7123
25.	UNIVERSITY OF PRETORIA	PROF. PEPPER	072 209 6324
26.	WPBTS	DR ARTHUR BIRD	

#### 4. FINANCIAL IMPLICATIONS FOR THE STATE

The amounts indicated in the table below have been allocated by National Treasury for the new Office as well as for ongoing National Department of Health functions.

	<i>11/12 (R'000)</i>	<i>12/13 (R'000)</i>	<i>13/14 (R'000)</i>
Total budget	R28 million	R48 million	R40 million

#### 5. PARLIAMENTARY PROCEDURE

- 5.1 The Department of Health and the State Law Advisers are of the opinion that this Bill must be dealt with in accordance with the procedure established by section 76(1) or (2) of the Constitution of the Republic of South Africa, 1996, since it falls within a functional area listed in Schedule 4 to the Constitution, namely "Health services".
- 5.2 The State Law Advisers are also of the opinion that it is not necessary to refer this Bill to the National House of Traditional Leaders in terms of section 18(1)(a) of the Traditional Leadership and Government Framework Act, 2003 (Act. No. 41 of 2003), since it does not contain provisions pertaining to customary law or customs of traditional communities.