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THE PRESIDENCY

No. 869

23 July 2004

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:—

No. 61 of 2003: National Health Act, 2004.



AIDS HELPLINE: 0800-123-22 Prevention is the cure

*(English text signed by the President.)
(Assented to 18 July 2004.)*

ACT

To provide a framework for a structured uniform health system within the Republic, taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services; and to provide for matters connected therewith.

PREAMBLE

RECOGNISING—

- * the socio-economic injustices, imbalances and inequities of health services of the past;
- * the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights;
- * the need to improve the quality of life of all citizens and to free the potential of each person;

BEARING IN MIND THAT—

- * the State must, in compliance with section 7(2) of the Constitution, respect, protect, promote and fulfil the rights enshrined in the Bill of Rights, which is a cornerstone of democracy in South Africa;
- * in terms of section 27(2) of the Constitution the State must take reasonable legislative and other measures within its available resources to achieve the progressive realisation of the right of the people of South Africa to have access to health care services, including reproductive health care;
- * section 27(3) of the Constitution provides that no one may be refused emergency medical treatment;
- * in terms of section 28(1)(c) of the Constitution every child has the right to basic health care services;
- * in terms of section 24(a) of the Constitution everyone has the right to an environment that is not harmful to their health or well-being;

AND IN ORDER TO—

- * unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- * provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;

- * establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourages participation;
- * promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans,

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

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SCHEDULE

Definitions

1. In this Act, unless the context indicates otherwise—
- “**authorised institution**” means any institution designated as an authorised institution in terms of section 54; 10
- “**blood product**” means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;
- “**central hospital**” means a public hospital designated by the Minister to provide health services to users from more than one province; 15
- “**certificate of need**” means a certificate contemplated in section 36;
- “**communicable disease**” means a disease resulting from an infection due to pathogenic agents or toxins generated by the infection, following the direct or indirect transmission of the agents from the source to the host; 20
- “**Constitution**” means the Constitution of the Republic of South Africa, 1996 (Act No. 108 of 1996);
- “**death**” means brain death;
- “**Director-General**” means the head of the national department;
- “**district health council**” means a council established in terms of section 31; 25
- “**essential health services**” means those health services prescribed by the Minister to be essential health services after consultation with the National Health Council;
- “**embryo**” means a human offspring in the first eight weeks from conception;
- “**Forum of Statutory Health Professional Councils**” means the Forum established by section 50; 30
- “**gamete**” means either of the two generative cells essential for human reproduction;
- “**gonad**” means a human testis or human ovary;
- “**health agency**” means any person other than a health establishment— 35
- (a) whose business involves the supply of health care personnel to users or health establishments;
- (b) who employs health care personnel for the purpose of providing health services; or
- (c) who procures health care personnel or health services for the benefit of a user, and includes a temporary employment service as defined in the Basic Conditions of Employment Act, 1997 (Act No. 75 of 1997), involving health workers or health care providers; 40
- “**health care personnel**” means health care providers and health workers;
- “**health care provider**” means a person providing health services in terms of any law, including in terms of the— 45
- (a) Allied Health Professions Act, 1982 (Act No. 63 of 1982);
- (b) Health Professions Act, 1974 (Act No. 56 of 1974);
- (c) Nursing Act, 1978 (Act No. 50 of 1978);
- (d) Pharmacy Act, 1974 (Act No. 53 of 1974); and
- (e) Dental Technicians Act, 1979 (Act No. 19 of 1979); 50

- “**health district**” means a district contemplated in section 29;
- “**health establishment**” means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services; 5
- “**health nuisance**” means a situation, or state of affairs, that endangers life or health or adversely affects the well-being of a person or community;
- “**health officer**” means any person appointed as a health officer under section 80 or designated as such in terms of that section; 10
- “**health research**” includes any research which contributes to knowledge of—
- (a) the biological, clinical, psychological or social processes in human beings;
 - (b) improved methods for the provision of health services;
 - (c) human pathology;
 - (d) the causes of disease; 15
 - (e) the effects of the environment on the human body;
 - (f) the development or new application of pharmaceuticals, medicines and related substances; and
 - (g) the development of new applications of health technology;
- “**health research ethics committee**” means any committee registered in terms of section 73; 20
- “**health services**” means—
- (a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;
 - (b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution; 25
 - (c) medical treatment contemplated in section 35(2)(e) of the Constitution; and
 - (d) municipal health services;
- “**health technology**” means machinery or equipment that is used in the provision of health services, but does not include medicine as defined in section 1 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965); 30
- “**health worker**” means any person who is involved in the provision of health services to a user, but does not include a health care provider;
- “**hospital**” means a health establishment which is classified as a hospital by the Minister in terms of section 35; 35
- “**Inspectorate for Health Establishments**” means any inspectorate established in terms of section 77;
- “**military health establishment**” means a health establishment which is, in terms of the Constitution and the Defence Act, 2002 (Act No. 42 of 2002), the responsibility of and under the direct or indirect authority and control of the President, as Commander in Chief, and the Minister of Defence, and includes— 40
- (a) the Institutes for Aviation and Maritime Medicine;
 - (b) the Military Psychological Institute;
 - (c) military laboratory services; and
 - (d) military training and educational centres; 45
- “**Minister**” means the Cabinet member responsible for health;
- “**municipal council**” means a municipal council contemplated in section 157(1) of the Constitution;

“**municipal health services**”, for the purposes of this Act, includes—

- (a) water quality monitoring;
- (b) food control;
- (c) waste management;
- (d) health surveillance of premises; 5
- (e) surveillance and prevention of communicable diseases, excluding immunisations;
- (f) vector control;
- (g) environmental pollution control;
- (h) disposal of the dead; and 10
- (i) chemical safety,

but excludes port health, malaria control and control of hazardous substances;

“**municipality**” means a municipality as defined in section 1 of the Local Government: Municipal Systems Act, 2000 (Act No. 32 of 2000);

“**national department**” means the national Department of Health; 15

“**National Health Council**” means the Council established by section 22(1);

“**national health policy**” means all policies relating to issues of national health as approved by the Minister;

“**National Health Research Committee**” means the Committee established in terms of section 69(1); 20

“**National Health Research Ethics Council**” means the Council established by section 72(1);

“**national health system**” means the system within the Republic, whether within the public or private sector, in which the individual components are concerned with the financing, provision or delivery of health services; 25

“**non-communicable disease**” means a disease or health condition that cannot be contracted from another person, an animal or directly from the environment;

“**norm**” means a statistical normative rate of provision or measurable target outcome over a specified period of time;

“**Office of Standards Compliance**” means the Office established in terms of section 78(1); 30

“**oocyte**” means a developing human egg cell;

“**organ**” means any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete; 35

“**organ of state**” means an organ of state as defined in section 239 of the Constitution;

“**pollution**” means pollution as defined in section 1 of the National Environmental Management Act, 1998 (Act No. 107 of 1998);

“**premises**” means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance or ship; 40

“**prescribed**” means prescribed by regulation made under section 90;

“**primary health care services**” means such health services as may be prescribed by the Minister to be primary health care services; 45

“**private health establishment**” means a health establishment that is not owned or controlled by an organ of state;

“**provincial department**” means any provincial department responsible for health;

- “**Provincial Health Council**” means a Council established by section 26(1);
- “**public health establishment**” means a health establishment that is owned or controlled by an organ of state;
- “**rehabilitation**” means a goal-orientated and time-limited process aimed at enabling impaired persons to reach an optimum mental, physical or social functional level; 5
- “**relevant member of the Executive Council**” means the member of the Executive Council of a province responsible for health;
- “**statutory health professional council**” means—
- (a) the Health Professions Council of South Africa established by section 2 of the Health Professions Act, 1974 (Act No. 56 of 1974); 10
- (b) the South African Nursing Council established by section 2 of the Nursing Act, 1978 (Act No. 50 of 1978);
- (c) the South African Pharmacy Council established by section 2 of the Pharmacy Act, 1974 (Act No. 53 of 1974); 15
- (d) the Allied Health Professions Council of South Africa established by section 2 of the Allied Health Professions Act, 1982 (Act No. 63 of 1982);
- (e) the South African Dental Technicians Council contemplated in section 2 of the Dental Technicians Act, 1979 (Act No. 19 of 1979); and
- (f) such other statutory health professional council as the Minister may prescribe: 20
- “**this Act**” includes any regulation made thereunder;
- “**tissue**” means human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete;
- “**use**”, in relation to tissue, includes preserve or dissect;
- “**user**” means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is— 25
- (a) below the age contemplated in section 39(4) of the Child Care Act, 1983 (Act No. 74 of 1983), “user” includes the person’s parent or guardian or another person authorised by law to act on the firstmentioned person’s behalf; or 30
- (b) incapable of taking decisions, “user” includes the person’s spouse or partner or, in the absence of such spouse or partner, the person’s parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the firstmentioned person’s behalf;
- “**zygote**” means the product of the union of a male and a female gamete. 35

CHAPTER 1

OBJECTS OF ACT, RESPONSIBILITY FOR HEALTH AND ELIGIBILITY FOR FREE HEALTH SERVICES

Objects of Act

2. The objects of this Act are to regulate national health and to provide uniformity in respect of health services across the nation by— 40

- (a) establishing a national health system which—
- (i) encompasses public and private providers of health services; and

- (ii) provides in an equitable manner the population of the Republic with the best possible health services that available resources can afford;
- (b) setting out the rights and duties of health care providers, health workers, health establishments and users; and
- (c) protecting, respecting, promoting and fulfilling the rights of— 5
 - (i) the people of South Africa to the progressive realisation of the constitutional right of access to health care services, including reproductive health care;
 - (ii) the people of South Africa to an environment that is not harmful to their health or well-being; 10
 - (iii) children to basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution; and
 - (iv) vulnerable groups such as women, children, older persons and persons with disabilities.

Responsibility for health 15

3. (1) The Minister must, within the limits of available resources—
- (a) endeavour to protect, promote, improve and maintain the health of the population;
 - (b) promote the inclusion of health services in the socio-economic development plan of the Republic; 20
 - (c) determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population;
 - (d) ensure the provision of such essential health services, which must at least include primary health care services, to the population of the Republic as may be prescribed after consultation with the National Health Council; and 25
 - (e) equitably prioritise the health services that the State can provide.

(2) The national department, every provincial department and every municipality must establish such health services as are required in terms of this Act, and all health establishments and health care providers in the public sector must equitably provide health services within the limits of available resources. 30

Eligibility for free health services in public health establishments

4. (1) The Minister, after consultation with the Minister of Finance, may prescribe conditions subject to which categories of persons are eligible for such free health services at public health establishments as may be prescribed.

(2) In prescribing any condition contemplated in subsection (1), the Minister must have regard to— 35

- (a) the range of free health services currently available;
- (b) the categories of persons already receiving free health services;
- (c) the impact of any such condition on access to health services; and
- (d) the needs of vulnerable groups such as women, children, older persons and persons with disabilities. 40

(3) Subject to any condition prescribed by the Minister, the State and clinics and community health centres funded by the State must provide—

- (a) pregnant and lactating women and children below the age of six years, who are not members or beneficiaries of medical aid schemes, with free health services; 45
- (b) all persons, except members of medical aid schemes and their dependants and persons receiving compensation for compensable occupational diseases, with free primary health care services; and

- (c) women, subject to the Choice on Termination of Pregnancy Act, 1996 (Act No. 92 of 1996), free termination of pregnancy services.

CHAPTER 2

RIGHTS AND DUTIES OF USERS AND HEALTH CARE PERSONNEL

Emergency treatment

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5. A health care provider, health worker or health establishment may not refuse a person emergency medical treatment.

User to have full knowledge

6. (1) Every health care provider must inform a user of—
- (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user; 10
 - (b) the range of diagnostic procedures and treatment options generally available to the user;
 - (c) the benefits, risks, costs and consequences generally associated with each option; and 15
 - (d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

(2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy. 20

Consent of user

7. (1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless—

- (a) the user is unable to give informed consent and such consent is given by a person— 25
 - (i) mandated by the user in writing to grant consent on his or her behalf; or
 - (ii) authorised to give such consent in terms of any law or court order;
- (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed; 30
- (c) the provision of a health service without informed consent is authorised in terms of any law or a court order; 35
- (d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or
- (e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service. 40

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.

(3) For the purposes of this section “informed consent” means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.

Participation in decisions

8. (1) A user has the right to participate in any decision affecting his or her personal health and treatment. 5

(2) (a) If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.

(b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7. 10

(3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user’s best interest. 15

Health service without consent

9. (1) Subject to any applicable law, where a user is admitted to a health establishment without his or her consent, the health establishment must notify the head of the provincial department in the province in which that health establishment is situated within 48 hours after the user was admitted of the user’s admission and must submit such other information as may be prescribed. 20

(2) If the 48-hour-period contemplated in subsection (1) expires on a Saturday, Sunday or public holiday, the health establishment must notify the head of the provincial department of the user’s admission and must submit the other information contemplated in subsection (1) at any time before noon of the next day that is not a Saturday, Sunday or public holiday. 25

(3) Subsection (1) does not apply if the user consents to the provision of any health service in that health establishment within 24 hours of admission.

Discharge reports 30

10. (1) A health care provider must provide a user with a discharge report at the time of the discharge of the user from a health establishment containing such information as may be prescribed.

(2) In prescribing the information contemplated in subsection (1), the Minister must have regard to— 35

(a) the nature of the health service rendered;

(b) the prognosis for the user; and

(c) the need for follow-up treatment.

(3) A discharge report provided to a user may be verbal in the case of an outpatient, but must be in writing in the case of an inpatient. 40

Health services for experimental or research purposes

11. (1) Before a health establishment provides a health service for experimental or research purposes to any user and subject to subsection (2), the health establishment must inform the user in the prescribed manner that the health service is for experimental or research purposes or part of an experimental or research project. 45

(2) A health establishment may not provide any health service to a user for a purpose contemplated in subsection (1) unless the user, the health care provider primarily responsible for the user’s treatment, the head of the health establishment in question and the relevant health research ethics committee, or any other person to whom that

authority has been delegated, has given prior written authorisation for the provision of the health service in question.

Duty to disseminate information

12. The national department and every provincial department, district health council and municipality must ensure that appropriate, adequate and comprehensive information is disseminated on the health services for which they are responsible, which must include— 5

- (a) the types and availability of health services;
- (b) the organisation of health services;
- (c) operating schedules and timetables of visits; 10
- (d) procedures for access to the health services;
- (e) other aspects of health services which may be of use to the public;
- (f) procedures for laying complaints; and
- (g) the rights and duties of users and health care providers.

Obligation to keep record 15

13. Subject to National Archives of South Africa Act, 1996 (Act No. 43 of 1996), and the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), the person in charge of a health establishment must ensure that a health record containing such information as may be prescribed is created and maintained at that health establishment for every user of health services. 20

Confidentiality

14. (1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.

(2) Subject to section 15, no person may disclose any information contemplated in subsection (1) unless— 25

- (a) the user consents to that disclosure in writing;
- (b) a court order or any law requires that disclosure; or
- (c) non-disclosure of the information represents a serious threat to public health.

Access to health records

15. (1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interests of the user. 30

(2) For the purpose of this section, "personal information" means personal information as defined in section 1 of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000). 35

Access to health records by health care provider

16. (1) A health care provider may examine a user's health records for the purposes of— 40

- (a) treatment with the authorisation of the user; and

(b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.

(2) If the study, teaching or research contemplated in subsection (1)(b) reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection. 5

Protection of health records

17. (1) The person in charge of a health establishment in possession of a user's health records must set up control measures to prevent unauthorised access to those records and to the storage facility in which, or system by which, records are kept. 10

(2) Any person who—

- (a) fails to perform a duty imposed on them in terms of subsection (1);
- (b) falsifies any record by adding to or deleting or changing any information contained in that record;
- (c) creates, changes or destroys a record without authority to do so; 15
- (d) fails to create or change a record when properly required to do so;
- (e) provides false information with the intent that it be included in a record;
- (f) without authority, copies any part of a record;
- (g) without authority connects the personal identification elements of a user's record with any element of that record that concerns the user's condition, treatment or history; 20
- (h) gains unauthorised access to a record or record-keeping system, including intercepting information being transmitted from one person, or one part of a record-keeping system, to another;
- (i) without authority, connects any part of a computer or other electronic system on which records are kept to— 25
 - (i) any other computer or other electronic system; or
 - (ii) any terminal or other installation connected to or forming part of any other computer or other electronic system; or
- (j) without authority, modifies or impairs the operation of— 30
 - (i) any part of the operating system of a computer or other electronic system on which a user's records are kept; or
 - (ii) any part of the programme used to record, store, retrieve or display information on a computer or other electronic system on which a user's records are kept. 35

commits an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding one year or to both a fine and such imprisonment.

Laying of complaints

18. (1) Any person may lay a complaint about the manner in which he or she was treated at a health establishment and have the complaint investigated. 40

(2) The relevant member of the Executive Council and every municipal council must establish a procedure for the laying of complaints within those areas of the national health system for which they are responsible.

(3) The procedures for laying complaints must—

- (a) be displayed by all health establishments in a manner that is visible for any person entering the establishment and the procedure must be communicated to users on a regular basis; 45
- (b) in the case of a private health establishment, allow for the laying of complaints with the head of the relevant establishment;

- (c) include provisions for the acceptance and acknowledgment of every complaint directed to a health establishment, whether or not it falls within the jurisdiction or authority of that establishment; and
- (d) allow for the referral of any complaint that is not within the jurisdiction or authority of the health establishment to the appropriate body or authority. 5
- (4) In laying a complaint, the person contemplated in subsection (1) must follow the procedure established by the relevant member of the Executive Council or the relevant municipal council, as the case may be.

Duties of users

19. A user must— 10
- (a) adhere to the rules of the health establishment when receiving treatment or using health services at the health establishment;
- (b) subject to section 14 provide the health care provider with accurate information pertaining to his or her health status and co-operate with health care providers when using health services; 15
- (c) treat health care providers and health workers with dignity and respect; and
- (d) sign a discharge certificate or release of liability if he or she refuses to accept recommended treatment.

Rights of health care personnel

20. (1) Health care personnel may not be unfairly discriminated against on account of their health status. 20
- (2) Despite subsection (1) but subject to any applicable law, the head of the health establishment concerned may in accordance with any guidelines determined by the Minister impose conditions on the service that may be rendered by a health care provider or health worker on the basis of his or her health status. 25
- (3) Subject to any applicable law, every health establishment must implement measures to minimise—
- (a) injury or damage to the person and property of health care personnel working at that establishment; and
- (b) disease transmission. 30
- (4) A health care provider may refuse to treat a user who is physically or verbally abusive or who sexually harasses him or her.

CHAPTER 3

NATIONAL HEALTH

General functions of national department 35

21. (1) The Director-General must—
- (a) ensure the implementation of national health policy in so far as it relates to the national department; and
- (b) issue guidelines for the implementation of national health policy.
- (2) The Director-General must, in accordance with national health policy— 40
- (a) liaise with national health departments in other countries and with international agencies;
- (b) issue, and promote adherence to, norms and standards on health matters, including— 45
- (i) nutritional intervention;
- (ii) environmental conditions that constitute a health hazard;
- (iii) the use, donation and procurement of human tissue, blood, blood products and gametes;
- (iv) sterilisation and termination of pregnancy;

- (v) the provision of health services, including social, physical and mental health care;
 - (vi) health services for convicted persons and persons awaiting trial;
 - (vii) genetic services; and
 - (viii) any other matter that affects the health status of people in more than one province; 5
 - (c) promote adherence to norms and standards for the training of human resources for health;
 - (d) identify national health goals and priorities and monitor the progress of their implementation; 10
 - (e) co-ordinate health and medical services during national disasters;
 - (f) participate in intersectoral and interdepartmental collaboration;
 - (g) promote health and healthy lifestyles;
 - (h) promote community participation in the planning, provision and evaluation of health services; 15
 - (i) conduct and facilitate health systems research in the planning, evaluation and management of health services;
 - (j) facilitate the provision of indoor and outdoor environmental pollution control services;
 - (k) facilitate and promote the provision of health services for the management, prevention and control of communicable and non-communicable diseases; and 20
 - (l) co-ordinate health services rendered by the national department with the health services rendered by provinces and provide such additional health services as may be necessary to establish a comprehensive national health system. 25
- (3) (a) The Director-General must prepare strategic, medium term health and human resources plans annually for the exercise of the powers and the performance of the duties of the national department.
- (b) The national health plans referred to in paragraph (a) must form the basis of— 30
- (i) the annual budget as required by the national department responsible for finance and state expenditure; and
 - (ii) any other governmental planning exercise as may be required by any other law.
- (4) The national health plans must comply with national health policy. 35
- (5) The Director-General must integrate the health plans of the national department and provincial departments annually and submit the integrated health plans to the National Health Council.

Establishment and composition of National Health Council

22. (1) A council to be known as the National Health Council is hereby established. 40
- (2) The National Health Council consists of—
- (a) the Minister, or his or her nominee, who acts as chairperson;
 - (b) the Deputy Minister of Health, if there is one;
 - (c) the relevant members of the Executive Councils;
 - (d) one municipal councillor, representing organised local government and appointed by the national organisation contemplated in section 163(a) of the Constitution; 45
 - (e) the Director-General and the Deputy Directors-General of the national department;
 - (f) the head of each provincial department; 50
 - (g) one person employed and appointed by the national organisation contemplated in section 163(a) of the Constitution; and
 - (h) the head of the South African Military Health Service.

Functions of National Health Council

23. (1) The National Health Council must advise the Minister on—
- (a) policy concerning any matter that will protect, promote, improve and maintain the health of the population, including—
 - (i) responsibilities for health by individuals and the public and private sector; 5
 - (ii) targets, priorities, norms and standards relating to the equitable provision and financing of health services;
 - (iii) efficient co-ordination of health services;
 - (iv) human resources planning, production, management and development; 10
 - (v) development, procurement and use of health technology;
 - (vi) equitable financial mechanisms for the funding of health services;
 - (vii) the design and implementation of programmes to provide for effective referral of users between health establishments or health care providers, or to enable integration of public and private health establishments; 15
 - (viii) financial and other assistance received from foreign governments and intergovernmental or nongovernmental organisations, the conditions applicable to receiving such assistance and the mechanisms to ensure compliance with these conditions;
 - (ix) epidemiological surveillance and monitoring of national and provincial trends with regard to major diseases and risk factors for disease; and 20
 - (x) obtaining, processing and use of statistical returns;
 - (b) proposed legislation pertaining to health matters prior to such legislation being introduced into Parliament or a provincial legislature;
 - (c) norms and standards for the establishment of health establishments; 25
 - (d) guidelines for the management of health districts;
 - (e) the implementation of national health policy;
 - (f) the national and provincial integrated health plans contemplated in section 21(5);
 - (g) an integrated national strategy for health research; and 30
 - (h) the performance of any other function determined by the Minister.
- (2) The National Health Council may determine the time frames, guidelines and the format for the preparation of national and provincial health plans.
- (3) The National Health Council must strive to reach its decisions by consensus but where a decision cannot be reached by consensus, the decision of the majority of the members of the National Health Council is the decision of the National Health Council. 35
- (4) The National Health Council may consult with or receive representations from any person, organisation, institution or authority.
- (5) The National Health Council may create one or more committees to advise it on any matter. 40
- (6) The National Health Council determines the procedures for its meetings.
- (7) A quorum for the National Health Council is at least half of the members plus one.
- (8) The Minister or his or her nominee contemplated in section 22(2)(a) must convene the first meeting of the National Health Council within 60 days of the commencement of this Act. 45

National Consultative Health Forum

24. (1) The Minister must establish a body to be known as the National Consultative Health Forum.

(2) The National Consultative Health Forum must promote and facilitate interaction, communication and the sharing of information on national health issues between 50

representatives of the national department, national organisations identified by the Minister and provincial consultative bodies contemplated in section 28.

(3) (a) Subject to paragraphs (b) and (c), the Minister must determine the composition and the place, date and time of any meeting of the National Consultative Health Forum.

(b) The National Consultative Health Forum must include relevant stakeholders. 5

(c) The National Consultative Health Forum must meet at least once every 12 months.

CHAPTER 4

PROVINCIAL HEALTH

Provincial health services, and general functions of provincial departments

25. (1) The relevant member of the Executive Council must ensure the implementation of national health policy, norms and standards in his or her province. 10

(2) The head of a provincial department must, in accordance with national health policy and the relevant provincial health policy in respect of or within the relevant province --

(a) provide specialised hospital services; 15

(b) plan and manage the provincial health information system;

(c) participate in interprovincial and intersectoral co-ordination and collaboration;

(d) co-ordinate the funding and financial management of district health councils;

(e) provide technical and logistical support to district health councils;

(f) plan, co-ordinate and monitor health services and must evaluate the rendering of health services; 20

(g) co-ordinate health and medical services during provincial disasters;

(h) conduct or facilitate research on health and health services;

(i) plan, manage and develop human resources for the rendering of health services; 25

(j) plan the development of public and private hospitals, other health establishments and health agencies;

(k) control and manage the cost and financing of public health establishments and public health agencies;

(l) facilitate and promote the provision of port health services, comprehensive primary health services and community hospital services; 30

(m) provide and co-ordinate emergency medical services and forensic pathology, forensic clinical medicines and related services, including the provision of medico-legal mortuaries and medico-legal services;

(n) control the quality of all health services and facilities; 35

(o) provide health services contemplated by specific provincial health service programmes;

(p) provide and maintain equipment, vehicles and health care facilities in the public sector;

(q) consult with communities regarding health matters; 40

(r) provide occupational health services;

(s) promote health and healthy lifestyles;

(t) promote community participation in the planning, provision and evaluation of health services;

(u) provide environmental pollution control services; 45

(v) ensure health systems research; and

- (w) provide services for the management, prevention and control of communicable and non-communicable diseases.
- (3) The head of a provincial department must—
 - (a) prepare strategic, medium term health and human resources plans annually for the exercise of the powers of, the performance of the duties of and the provision of health services in the province by the provincial department; and
 - (b) submit such plans to the Director-General within the time frames and in accordance with the guidelines determined by the National Health Council.
- (4) Provincial health plans must conform with national health policy.

Establishment and composition of Provincial Health Council 10

26. (1) A council to be known as the Provincial Health Council is hereby established in each province.
- (2) Every Provincial Health Council consists of—
- (a) the relevant member of the Executive Council, or his or her nominee, who acts as chairperson;
 - (b) one Councillor from each of the metropolitan municipalities in the province if there are such municipalities in the province in question;
 - (c) one Councillor from each of the district municipalities in the province;
 - (d) the head of the provincial department;
 - (e) not more than three representatives involved in the management of local government; and
 - (f) such number of other persons as the relevant member of the Executive Council may consider appropriate.
- (3) The persons contemplated in subsection (2)(e) must be appointed by the national and relevant provincial organisation contemplated in section 163(a) of the Constitution.

Functions of Provincial Health Council

27. (1) A Provincial Health Council must advise the relevant member of the Executive Council on—
- (a) policy concerning any matter that will protect, promote, improve and maintain the health of the population within the province, including—
 - (i) responsibilities for health within the province by individuals and the public and private sector;
 - (ii) targets, priorities, norms and standards within the province relating to the equitable provision and financing of health services;
 - (iii) efficient co-ordination of health services within the province and between neighbouring provinces;
 - (iv) human resources planning, production, management and development;
 - (v) development, procurement and use of health technology within the province;
 - (vi) equitable financial mechanisms for the funding of health services within the province;
 - (vii) the design and implementation of programmes within the province to provide for effective referral of users between health establishments or health care providers or to enable integration of public and private health establishments;
 - (viii) financial and other assistance received by the province from foreign governments and intergovernmental or nongovernmental organisations, the conditions applicable to receiving such assistance and the mechanisms to ensure compliance with these conditions;
 - (ix) epidemiological surveillance and monitoring of provincial trends with regard to major diseases and risk factors for disease; and
 - (x) obtaining, processing and use of statistical returns;
 - (b) proposed legislation relating to health matters before it is introduced in the relevant provincial legislature;
 - (c) norms and standards for the establishment of health establishments;

- (d) guidelines for the management of health districts;
- (e) the implementation of national and provincial health policy; and
- (f) the performance of any other function determined by the relevant member of the Executive Council.

(2) A Provincial Health Council may determine the time frames, guidelines and the format for the preparation of district health plans within its jurisdiction. 5

(3) A Provincial Health Council may consult with or receive representations from any person, organisation, institution or authority.

(4) A Provincial Health Council determines the procedures for its meetings.

(5) The Provincial Health Council may create one or more committees to advise it on any matter. 10

(6) A quorum of a Provincial Health Council is at least half of the members plus one.

(7) The relevant member of the Executive Council or his or her nominee contemplated in section 26(2)(a) must convene the first meeting of the Provincial Health Council within 90 days of commencement of this Act. 15

Provincial consultative bodies

28. (1) The relevant member of the Executive Council must establish a consultative body for his or her province.

(2) A provincial consultative body must promote and facilitate interaction, communication and the sharing of information on provincial health issues between representatives of the provincial department and provincial and municipal organisations identified by the relevant member of the Executive Council. 20

(3) (a) Subject to paragraphs (b) and (c) the relevant member of the Executive Council must determine the composition and the place, date and time of any meeting of the provincial consultative body in his or her province. 25

(b) A provincial consultative body must include relevant stakeholders.

(c) A provincial consultative body must meet at least once every 12 months.

CHAPTER 5

DISTRICT HEALTH SYSTEM

Establishment of district health system 30

29. (1) A district health system is hereby established.

(2) The system consists of various health districts, and the boundaries of health districts coincide with district and metropolitan municipal boundaries.

Division of health districts into subdistricts

30. (1) (a) The relevant member of the Executive Council may, with the concurrence of the member of the Executive Council responsible for local government in the province in question and subject to subsection (2), divide any health district in the province into subdistricts and may determine and change the boundaries of such subdistricts. 35

(b) Where a health district falls within more than one province, the members of the Executive Council of all the relevant provinces must agree to any division, determination or change contemplated in paragraph (a). 40

(c) Details of any division, determination or change must be published in the *Gazette*.

(2) The members contemplated in subsection (1) must have due regard to the principles laid down in sections 27 and 195 of the Constitution and the criteria laid down in section 25 of the Local Government: Municipal Demarcation Act, 1998 (Act No. 27 of 1998), particularly in so far as they relate to— 45

- (a) equity;
- (b) access to services;
- (c) quality;
- (d) overcoming fragmentation;
- (e) comprehensive services; 5
- (f) effectiveness;
- (g) efficiency;
- (h) local accountability;
- (i) community participation;
- (j) developmental and intersectoral approach; and 10
- (k) sustainability.

Establishment of district health councils

31. (1) The relevant member of the Executive Council, after consultation with the member of the Executive Council responsible for local government in the province in question and the municipal council of the relevant metropolitan or district municipality, must establish a district health council for every health district in his or her province. 15

(2) (a) A district health council consists of—

- (i) a member of the metropolitan or district municipal council situated in the health district in question, nominated by the relevant council;
- (ii) a person appointed by the relevant member of the Executive Council to represent him or her; 20
- (iii) a member of the council of each local municipality within the health district, nominated by the members of the relevant council; and
- (iv) not more than five other persons, appointed by the relevant member of the Executive Council after consultation with the municipal council of the metropolitan or district municipality, as the case may be. 25

(b) The member contemplated in paragraph (a)(i) is the chairperson of the district health council.

(c) In the case of a cross-boundary district, the relevant members of the Executive Council may each appoint a member to represent them and the persons contemplated in paragraph (a)(iv) must be appointed by the relevant members of the Executive Council in consultation with each other. 30

(3) A district health council must—

- (a) promote co-operative governance;
- (b) ensure co-ordination of planning, budgeting, provisioning and monitoring of all health services that affect residents of the health district for which the council was established; and 35
- (c) advise the relevant members of the Executive Council, through the Provincial Health Councils, and the municipal council of the relevant metropolitan or district municipality, on any matter regarding health or health services in the health district for which the council was established. 40

(4) A district health council may create one or more committees to advise it on any matter.

(5) Provincial legislation must at least provide for—

- (a) the functioning of district health councils; 45
- (b) the approval, after consultation with the relevant district health council, by the relevant member of the Executive Council and the municipal council of the metropolitan or district municipality, as the case may be, of the detailed budget and performance targets for health services in the health district to which both the provincial and municipal spheres of government must contribute; and 50
- (c) (i) deadlock-breaking mechanisms for cases where agreement between the relevant member of the Executive Council and the municipal council on the budget or performance targets contemplated in paragraph (b) cannot be reached within a period specified in the legislation; and 55
- (ii) corrective action to be taken if the agreement contemplated in subparagraph (i) is breached.

(6) The relevant member of the Executive Council must ensure that each health district and each health subdistrict is effectively managed.

Health services to be provided by municipalities

32. (1) Every metropolitan and district municipality must ensure that appropriate municipal health services are effectively and equitably provided in their respective areas. 5

(2) The relevant member of the Executive Council must assign such health services to a municipality in his or her province as are contemplated in section 156(4) of the Constitution.

(3) An agreement contemplated in section 156(4) of the Constitution is known as a service level agreement and must provide for— 10

- (a) the services to be rendered by the municipality;
- (b) the resources that the relevant member of the Executive Council must make available;
- (c) performance standards which must be used to monitor services rendered by the municipality; and 15
- (d) conditions under which the agreement may be terminated.

Preparation of district health plans

33. (1) Each district and metropolitan health manager must within the national budget cycle develop and present to the district health council in question and the relevant member of the Executive Council a district health plan drawn up in accordance with national guidelines issued by the Director-General with due regard to national and provincial health policies and the requirements of the relevant integrated development plan prepared in terms of section 25 of the Local Government: Municipal Systems Act, 2000 (Act No. 32 of 2000). 20 25

(2) The relevant member of the Executive Council must ensure that each health district develops and implements a district human resource plan in accordance with national guidelines issued by the Director-General.

Transitional arrangements concerning municipal health services

34. Until a service level agreement contemplated in section 32(3) is concluded, municipalities must continue to provide, within the resources available to them, the health services that they were providing in the year before this Act took effect. 30

CHAPTER 6

HEALTH ESTABLISHMENTS

Classification of health establishments 35

35. The Minister may by regulation—

- (a) classify all health establishments into such categories as may be appropriate, based on—
 - (i) their role and function within the national health system;
 - (ii) the size and location of the communities they serve; 40
 - (iii) the nature and level of health services they are able to provide;
 - (iv) their geographical location and demographic reach;
 - (v) the need to structure the delivery of health services in accordance with national norms and standards within an integrated and co-ordinated national framework; and 45
 - (vi) in the case of private health establishments, whether or not the establishment is for profit or not; and

- (b) in the case of a central hospital, determine the establishment of the hospital board and the management system of such central hospital.

Certificate of need

36. (1) A person may not—

- (a) establish, construct, modify or acquire a health establishment or health agency; 5
 (b) increase the number of beds in, or acquire prescribed health technology at, a health establishment or health agency;
 (c) provide prescribed health services; or
 (d) continue to operate a health establishment or health agency after the 10
 expiration of 24 months from the date this Act took effect,

without being in possession of a certificate of need.

(2) A person who wishes to obtain or renew a certificate of need must apply to the Director-General in the prescribed manner and must pay the prescribed application fee.

(3) Before the Director-General issues or renews a certificate of need, he or she must 15
 take into account—

- (a) the need to ensure consistency of health services development in terms of national, provincial and municipal planning;
 (b) the need to promote an equitable distribution and rationalisation of health services and health care resources, and the need to correct inequities based on 20
 racial, gender, economic and geographical factors;
 (c) the need to promote an appropriate mix of public and private health services;
 (d) the demographics and epidemiological characteristics of the population to be served;
 (e) the potential advantages and disadvantages for existing public and private 25
 health services and for any affected communities;
 (f) the need to protect or advance persons or categories of persons designated in terms of the Employment Equity Act, 1998 (Act No. 55 of 1998), within the emerging small, medium and micro-enterprise sector;
 (g) the potential benefits of research and development with respect to the 30
 improvement of health service delivery;
 (h) the need to ensure that ownership of facilities does not create perverse incentives for health service providers and health workers;
 (i) if applicable, the quality of health services rendered by the applicant in the 35
 past;
 (j) the probability of the financial sustainability of the health establishment or health agency;
 (k) the need to ensure the availability and appropriate utilisation of human resources and health technology;
 (l) whether the private health establishment is for profit or not; and 40
 (m) if applicable, compliance with the requirements of a certificate of non-compliance.

(4) The Director-General may investigate any issue relating to an application for the issue or renewal of a certificate of need and may call for such further information as may be necessary in order to make a decision upon a particular application. 45

(5) The Director-General may issue or renew a certificate of need subject to—

- (a) compliance by the holder with national operational norms and standards for health establishments and health agencies, as the case may be; and
 (b) any condition regarding—
 (i) the nature, type or quantum of services to be provided by the health 50
 establishment or health agency;
 (ii) human resources and diagnostic and therapeutic equipment and the deployment of human resources or the use of such equipment;

- (iii) public private partnerships;
 - (iv) types of training to be provided by the health establishment or health agency; and
 - (v) any criterion contemplated in subsection (3).
- (6) The Director-General may withdraw a certificate of need— 5
- (a) on the recommendation of the Office of Standards Compliance in terms of section 79(7)(b);
 - (b) if the continued operation of the health establishment or the health agency, as the case may be, or the activities of a health care provider or health worker working within the health establishment, constitute a serious risk to public health; 10
 - (c) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, is unable or unwilling to comply with minimum operational norms and standards necessary for the health and safety of users; or 15
 - (d) if the health establishment or the health agency, as the case may be, or a health care provider or health worker working within the health establishment, persistently violates the constitutional rights of users or obstructs the State in fulfilling its obligations to progressively realise the constitutional right of access to health services. 20
- (7) If the Director-General refuses an application for a certificate of need or withdraws a certificate of need the Director-General must within a reasonable time give the applicant or holder, as the case may be, written reasons for such refusal or withdrawal.

Duration of certificate of need 25

37. A certificate of need is valid for a prescribed period, but such prescribed period may not exceed 20 years.

Appeal to Minister against Director-General's decision

38. (1) Any person aggrieved by a decision of the Director-General in terms of section 36 may appeal in writing to the Minister against such decision. 30
- (2) Such appeal must—
- (a) be lodged within 60 days from the date on which written reasons for the decision were given by the Director-General or such later date as the Minister permits; and
 - (b) set out the grounds of appeal. 35
- (3) After considering the grounds of appeal and the Director-General's reasons for the decision, the Minister must as soon as practicable—
- (a) confirm, set aside or vary the decision; or
 - (b) substitute any other decision for the decision of the Director-General.
- (4) The Minister must within a reasonable time after reaching a decision give the appellant written reasons for such decision. 40

Regulations relating to certificates of need

39. (1) The Minister may, after consultation with the National Health Council, make regulations relating to—
- (a) the requirements for the issuing or renewal of a certificate of need; 45
 - (b) the requirements for a certificate of need for health establishments and health agencies existing at the time of commencement of this Act;
 - (c) the requirements for a certificate of need for health establishments and health agencies coming into being after the commencement of this Act; and

- (d) any other matter relating to the granting of a certificate of need and the inspection and administration of health establishments and health agencies.
- (2) Regulations made under subsection (1)—
- (a) must ensure the equitable distribution and rationalisation of health, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities; 5
- (b) may prescribe the fees payable in respect of applications for the issuing and renewal of certificates of need;
- (c) must prescribe the formats and procedures to be used in applications for the issuing and renewal of certificates of need, and the information that must be submitted with such applications; 10
- (d) must ensure and promote access to health services and the optimal utilisation of health care resources, with special regard to vulnerable groups such as woman, older persons, children and people with disabilities;
- (e) must ensure compliance with the provisions of this Act and national operational norms and standards for the delivery of health services; 15
- (f) must seek to avoid or prohibit business practices or perverse incentives which adversely affect the costs or quality of health services or the access of users to health services;
- (g) must avoid or prohibit practices, schemes or arrangements by health care providers or health establishments that directly or indirectly conflict with, violate or undermine good ethical and professional practice; and 20
- (h) must ensure that the quality of health services provided by health establishments and health agencies conforms to the prescribed norms and standards.

Offences and penalties in respect of certificate of need

25

40. (1) Any person who performs any act contemplated in section 36(1) without a certificate of need required in terms of that section is guilty of an offence.

(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 five years or to both a fine and such imprisonment. 30

Provision of health services at public health establishments

41. (1) The Minister, in respect of a central hospital, and the relevant member of the Executive Council, in respect of all other public health establishments within the province in question, may—

- (a) determine the range of health services that may be provided at the relevant public health establishment; 35
- (b) prescribe the procedures and criteria for admission to and referral from a public health establishment or group of public health establishments;
- (c) subject to subsection (2), prescribe schedules of fees, including penalties for not following the procedures contemplated in paragraph (b), for— 40
- (i) different categories of users;
- (ii) various forms of treatment; and
- (iii) various categories of public health establishments; and
- (d) in consultation with the relevant Treasury, determine the proportion of revenue generated by a particular public health establishment classified as a hospital that may be retained by that hospital, and how those funds may be used. 45

(2) When determining a schedule of fees, the fee for a particular service may not be varied in respect of users who are not ordinarily resident in a province.

(3) Despite subsection (2), a province whose residents make use of another province's services must compensate that province for health services provided to such residents in the manner and to the extent prescribed by the Minister in consultation with, in the case of a central hospital, the National Treasury and, in the case of any other hospital, the relevant Treasury. 5

(4) The Minister must appoint a representative hospital board for each central hospital or group of central hospitals.

(5) The functions of a central hospital board must be prescribed by the Minister.

(6) (a) The relevant member of the Executive Council must—

- (i) appoint a representative board for each public health establishment classified as a hospital or for each group of such public health establishments within the relevant province; 10
- (ii) prescribe the functions of such boards; and
- (iii) prescribe procedures for meetings of the board.

(b) A hospital contemplated in paragraph (a) does not include a central hospital. 15

(7) The boards contemplated in subsections (4) and (6) must be composed of—

- (a) one representative from each university associated with the hospital;
- (b) in the case of a board contemplated in subsection (4), one representative from the national department;
- (c) in the case of boards contemplated in subsections (4) and (6), one representative from the provincial department in the province in which the relevant hospital is situated; 20
- (d) not more than three representatives of the communities served by the hospital, including special interest groups representing users; and
- (e) not more than five representatives of staff and management of the hospital but such representatives may not vote at a meeting of the board. 25

(8) The boards contemplated in subsections (4) and (6) may include not more than five persons with expertise in areas such as accounting, financial management, human resources management, information management and legal matters.

(9) Members of a hospital board are appointed for a period of three years at a time and the Minister, in the case of central hospitals, or the relevant member of the Executive Council, in the case of other hospitals, may replace any member on good cause shown. 30

Clinics and community health centre committees

42. (1) Provincial legislation must at least provide for the establishment in the province in question of a committee for— 35

- (a) a clinic or a group of clinics;
- (b) a community health centre; or
- (c) a clinic and a community health centre or a group of clinics and community health centres.

(2) Any committee contemplated in subsection (1) must at least include— 40

- (a) one or more local government councillors;
- (b) one or more members of the community served by the health facility; and
- (c) the head of the clinic or health centre in question.

(3) The functions of a committee must be prescribed in the provincial legislation in question. 45

Health services at non-health establishments and at public health establishments other than hospitals

43. (1) The Minister may prescribe—

- (a) minimum standards and requirements for the provision of health services in locations other than health establishments, including schools and other public places; and 50

(b) penalties for any contravention of or failure to comply with any such standards or requirements.

(2) Provincial legislation must provide for the provision of health services at health establishments in the province in question other than hospitals.

(3) (a) The Minister may, in the interests of the health and wellbeing of persons attending an initiation school and subject to the provisions of any other law, prescribe conditions under which the circumcision of a person as part of an initiation ceremony may be carried out. 5

(b) For the purposes of this subsection—

(i) “initiation school” means any place at which one or more persons are circumcised as part of an initiation ceremony; and 10

(ii) “initiation ceremony” means a traditional ritual or practice in terms of which a person is inducted into an order or accorded a certain status or recognition within a community.

(4) The Minister may, subject to the provisions of any other law, prescribe conditions relating to traditional health practices to ensure the health and well-being of persons who are subject to such health practices. 15

Referral from one public health establishment to another

44. (1) Subject to this Act, a user may attend any public health establishment for the purposes of receiving health services. 20

(2) If a public health establishment is not capable of providing the necessary treatment or care, the public health establishment in question must transfer the user concerned to an appropriate public health establishment which is capable of providing the necessary treatment or care in such manner and on such terms as may be determined by the Minister or the relevant member of the Executive Council, as the case may be. 25

Relationship between public and private health establishments

45. (1) The Minister must prescribe mechanisms to enable a co-ordinated relationship between private and public health establishments in the delivery of health services.

(2) The national department, any provincial department or any municipality may enter into an agreement with any private practitioner, private health establishment or non-governmental organisation in order to achieve any object of this Act. 30

(3) An agreement contemplated in subsection (2) must comply with the Public Finance Management Act, 1999 (Act No. 1 of 1999), or any municipal finance management legislation, as the case may be.

Obligations of private health establishments 35

46. Every private health establishment must maintain insurance cover sufficient to indemnify a user for damages that he or she might suffer as a consequence of a wrongful act by any member of its staff or by any of its employees.

Evaluating services of health establishments

47. (1) All health establishments must comply with the quality requirements and standards prescribed by the Minister after consultation with the National Health Council. 40

(2) The quality requirements and standards contemplated in subsection (1) may relate to human resources, health technology, equipment, hygiene, premises, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated. 45

(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).

CHAPTER 7

HUMAN RESOURCES PLANNING AND ACADEMIC HEALTH COMPLEXES

Development and provision of human resources in national health system

48. (1) The National Health Council must develop policy and guidelines for, and monitor the provision, distribution, development, management and utilisation of, human resources within the national health system. 5

(2) The policy and guidelines contemplated in subsection (1) must amongst other things facilitate and advance—

- (a) the adequate distribution of human resources;
- (b) the provision of appropriately trained staff at all levels of the national health system to meet the population's health care needs; and 10
- (c) the effective and efficient utilisation, functioning, management and support of human resources within the national health system.

Maximising services of health care providers

49. The Minister, with the concurrence of the National Health Council, must determine guidelines to enable the provincial departments and district health councils to implement programmes for the appropriate distribution of health care providers and health workers. 15

Forum of Statutory Health Professional Councils

50. (1) A forum to be known as the Forum of Statutory Health Professional Councils is hereby established on which all the statutory health professional councils must be represented. 20

(2) The Forum of Statutory Health Professional Councils consists of the chairpersons of the statutory health professional councils and the registrars or chief executive officers, as the case may be, of the statutory health professional councils. 25

(3) (a) In addition to the representatives contemplated in subsection (2), the Minister must appoint—

- (i) two representatives of the national department;
 - (ii) three community representatives who have been appointed to any of the statutory health professional councils contemplated in subsection (1); and 30
 - (iii) two representatives of tertiary education institutions,
- to the Forum of Statutory Health Professional Councils.

(b) (i) The Minister must appoint a suitable person as chairperson of the Forum of Statutory Health Professional Councils.

(ii) The chairperson holds office for such period, but not exceeding two years, as the Minister may determine at the time of his or her appointment, and may be reappointed at the expiry of his or her term of office. 35

(c) Any member of the Forum of Statutory Health Professional Councils, including the chairperson, must vacate his or her office if—

- (i) his or her estate is sequestrated; 40
- (ii) he or she becomes disqualified from practising his or her profession in terms of any law;
- (iii) he or she becomes mentally ill to such a degree that it is necessary that he or she be detained, supervised or controlled;
- (iv) he or she is convicted in the Republic or elsewhere of an offence involving dishonesty or an offence in respect whereof he or she is sentenced to imprisonment without the option of a fine; 45
- (v) he or she ceases to be a South African citizen;
- (vi) he or she has been absent from more than two consecutive ordinary meetings of the Forum without leave from the Forum; 50
- (vii) he or she tenders his or her resignation in writing and the Minister accepts the resignation;

- (viii) he or she ceases to hold any qualification necessary for his or her appointment;
or
- (ix) the Minister, in the public interest, terminates his or her membership.
- (4) The Forum of Statutory Health Professional Councils must—
- (a) protect the interests of the public and users; 5
- (b) ensure communication and liaison between the statutory health professional councils upon matters affecting more than one of the registered professions;
- (c) in the interests of the public, promote interprofessional liaison and communication between registered professions;
- (d) promote good practice in health services and sharing of information between the statutory health professional councils; 10
- (e) ensure consistency in the actions and decisions of the statutory health professional councils;
- (f) consult and liaise with any relevant authority on matters collectively affecting all registered health professions; 15
- (g) investigate and report on, of its own accord, at the request of one or more of the statutory health professional councils or at the request of the Minister, any matter of relevance to more than one statutory health professional council;
- (h) in the prescribed manner, act as ombudsperson in respect of complaints by members of the public and other persons concerning the councils referred to in subsection (1); 20
- (i) advise the Minister on the development of coherent policies relating to the education and training and optimal utilisation and distribution of health care providers;
- (j) monitor and advise the Minister on the implementation of health policy in so far as it impacts on health care providers and the registered professions; 25
- (k) hold the statutory health professional councils explicitly to account for their performance as competent public authorities;
- (l) publish an annual report on the performance of the statutory health professional councils; 30
- (m) set performance improvement targets with the statutory health professional councils and monitor their progress; and
- (n) advise the Minister and the individual statutory health professional councils concerning—
- (i) the scopes of practice of the registered professions; 35
- (ii) common educational and training requirements of health care providers;
- (iii) new professions to be regulated;
- (iv) targets, priorities, norms and standards relating to the equitable distribution of health care providers;
- (v) development, procurement and use of health service technology; 40
- (vi) perverse incentives within the registered professions;
- (vii) the recruitment, evaluation and registration of foreign health care professionals;
- (viii) effective co-ordination of the objectives and responsibilities of the various statutory health professional councils; 45
- (ix) responsibilities of health care providers in promoting and maintaining public health;
- (x) interprofessional communication and relationships; and
- (xi) any other matter that may be prescribed.
- (5) (a) In performing its duties the Forum of Statutory Health Professional Councils may— 50
- (i) consult or hear representations by any person, body or authority; and
- (ii) establish a committee to advise it on any matter.
- (b) A committee contemplated in paragraph (a)(ii) may consist of not more than seven persons who must have the relevant knowledge, expertise, skills and experience to enable the committee to give the required advice. 55

- (c) The chairperson of the Forum must be a member of the committee.
- (6) (a) A decision of the Forum of Statutory Health Professional Councils must be taken by the votes of a majority of at least two thirds of the members of the Forum present at the meeting of the Forum.
- (b) A quorum for any meeting of the Forum is at least half of the members of the Forum plus one. 5
- (c) In the event of an equality of votes, the chairperson of the Forum has a casting vote in addition to his or her deliberative vote.
- (7) The Forum of Statutory Health Professional Councils may determine the procedure for its meetings. 10
- (8) The Forum of Statutory Health Professional Councils must meet at least three times a year.
- (9) The Forum of Statutory Health Professional Councils is funded through prescribed membership fees paid by the statutory health professional councils.
- (10) The members of the Forum of Statutory Health Professional Councils may agree that a person employed by one of the statutory health professional councils represented on the Forum must act as secretary at a meeting of the Forum. 15

Establishment of academic health complexes

51. The Minister may, in consultation with the Minister of Education, establish—
- (a) academic health complexes, which may consist of one or more health establishments at all levels of the national health system, including peripheral facilities, and one or more educational institutions working together to educate and train health care personnel and to conduct research in health services; and 20
- (b) any co-ordinating committees that may be necessary in order to perform such functions as may be prescribed. 25

Regulations relating to human resources

52. The Minister may make regulations regarding human resources within the national health system in order to—
- (a) ensure that adequate resources are available for the education and training of health care personnel to meet the human resources requirements of the national health system; 30
- (b) ensure the education and training of health care personnel to meet the requirements of the national health system;
- (c) create new categories of health care personnel to be educated or trained; 35
- (d) identify shortages of key skills, expertise and competencies within the national health system and to prescribe strategies which are not in conflict with the Higher Education Act, 1997 (Act No. 101 of 1997), for the—
- (i) recruitment of health care personnel from other countries; and
- (ii) education and training of health care providers or health workers in the Republic, 40
- to make up the deficit in respect of scarce skills, expertise and competencies;
- (e) prescribe strategies for the recruitment and retention of health care personnel within the national health system;
- (f) ensure the existence of adequate human resources planning, development and management structures at national, provincial and district levels of the national health system; 45
- (g) ensure the availability of institutional capacity at national, provincial and district levels of the national health system to plan for, develop and manage human resources; 50
- (h) ensure the definition and clarification of the roles and functions of the national department, provincial departments and municipalities with regard to the planning, production and management of human resources; and

- (i) prescribe circumstances under which health care personnel may be recruited from other countries to provide health services in the Republic.

CHAPTER 8

CONTROL OF USE OF BLOOD, BLOOD PRODUCTS, TISSUE AND GAMETES IN HUMANS

5

Establishment of national blood transfusion service

53. (1) The Minister must establish a blood transfusion service for the Republic by granting a licence to a non-profit organisation, which is able to provide a blood transfusion service throughout the territory of the Republic.

(2) The holder of the licence granted in terms of subsection (1)—

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- (a) must comply with prescribed norms and standards and must provide the prescribed blood transfusion and related services;
- (b) may establish regional units, for the delivery of blood transfusion services, which must function under the control of the licence holder; and
- (c) has the sole right to provide a blood transfusion service in the Republic.

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(3) Any person other than the holder of the licence granted in terms of subsection (1) who provides a blood transfusion service in the Republic, is guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

Designation of authorised institution

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54. (1) The Minister may, by notice in the *Gazette*, designate any institution other than an institution contemplated in section 63 as an authorised institution.

(2) An authorised institution may—

- (a) acquire, use or supply the body of a deceased person for any of the purposes referred to in section 64;
- (b) acquire or use any tissue lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in section 56 or 64, as the case may be;
- (c) supply any tissue preserved by it to an institution or person contemplated in section 63 for any of the purposes referred to in section 58 or 64; and
- (d) acquire, use and supply blood products for any of the purposes referred to in section 56 or 64.

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(3) The Minister may, in the notice contemplated in subsection (1), impose conditions in respect of the exercise of a power referred to in subsection (2).

Removal of tissue, blood, blood products or gametes from living persons

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55. A person may not remove tissue, blood, a blood product or gametes from the body of another living person for the purpose referred to in section 56 unless it is done—

- (a) with the written consent of the person from whom the tissue, blood, blood product or gametes are removed granted in the prescribed manner; and
- (b) in accordance with prescribed conditions.

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Use of tissue, blood, blood products or gametes removed or withdrawn from living persons

56. (1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed.

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(2) (a) Subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):

- (i) Tissue, blood, a blood product or a gamete from a person who is mentally ill within the meaning of the Mental Health Care Act, 2002 (Act No. 17 of 2002); 5
- (ii) tissue which is not replaceable by natural processes from a person younger than 18 years;
- (iii) a gamete from a person younger than 18 years; or
- (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells. 10

(b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect of such removal or withdrawal.

Prohibition of reproductive cloning of human beings

57. (1) A person may not— 15
- (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or
 - (b) engage in any activity, including nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being.
- (2) The Minister may, under such conditions as may be prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells. 20
- (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister.
- (4) The Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if— 25
- (a) the applicant undertakes to document the research for record purposes; and
 - (b) prior consent is obtained from the donor of such stem cells or zygotes.
- (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment. 30
- (6) For the purpose of this section—
- (a) “reproductive cloning of a human being” means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose; and
 - (b) “therapeutic cloning” means the manipulation of genetic material from either 35
- adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues.

Removal and transplantation of human tissue in hospital or authorised institution

58. (1) A person may not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except— 40
- (a) in a hospital or an authorised institution; and
 - (b) on the written authority of— 45
 - (i) the medical practitioner in charge of clinical services in that hospital or authorised institution, or any other medical practitioner authorised by him or her; or

- (ii) in the case where there is no medical practitioner in charge of the clinical services at that hospital or authorised institution, a medical practitioner authorised thereto by the person in charge of the hospital or authorised institution.

(2) The medical practitioner contemplated in subsection (1)(b) may not participate in a transplant for which he or she has granted authorisation in terms of that subsection. 5

Removal, use or transplantation of tissue, and administering of blood and blood products by medical practitioner or dentist

59. (1) For the purposes of this Chapter, only a registered medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes contemplated in section 56 or transplant tissue so removed into another living person. 10

(2) Subject to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), only a registered medical practitioner or dentist, or a person acting under the supervision or on the instructions of a medical practitioner or dentist, may for the purposes of this Chapter administer blood or a blood product to, or prescribe blood or a blood product for, a living person. 15

Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes

60. (1) No person, except— 20

(a) a hospital or an institution contemplated in section 58(1)(a), a person or an institution contemplated in section 63 and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another person for any of the purposes contemplated in section 56 or 64; 25

(b) a person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product. 30

(2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.

(3) This section does not prevent a health care provider registered with a statutory health professional council from receiving remuneration for any professional service rendered by him or her. 35

(4) It is an offence for a person—

(a) who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and 40

(b) to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.

(5) Any person convicted of an offence in terms of subsection (4) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment. 45

Allocation and use of human organs

61. (1) Human organs obtained from deceased persons for the purpose of transplantation or treatment, or medical or dental training or research, may only be used in the prescribed manner. 50

(2) Human organs obtained in terms of subsection (1) must be allocated in accordance with the prescribed procedures.

(3) An organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the Republic without the Minister's authorisation in writing.

(4) The Minister must prescribe—

- (a) criteria for the approval of organ transplant facilities; and
- (b) procedural measures to be applied for such approval.

(5) (a) A person who contravenes a provision of this section or fails to comply therewith or who charges a fee for a human organ is guilty of an offence. 5

(b) Any person convicted of an offence in terms of paragraph (a) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

Donation of human bodies and tissue of deceased persons

62. (1) (a) A person who is competent to make a will may— 10

- (i) in the will;
- (ii) in a document signed by him or her and at least two competent witnesses; or
- (iii) in an oral statement made in the presence of at least two competent witnesses,

donate his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose 15 provided for in this Act.

(b) A person who makes a donation as contemplated in paragraph (a) must nominate an institution or a person contemplated in section 63 as donee.

(c) If no donee is nominated in terms of paragraph (b), the donation is null and void.

(d) Paragraph (b) does not apply in respect of an organ donated for the purposes 20 contemplated in section 61(1) and the donee of such organ must be determined in terms of section 61(2).

(2) In the absence of a donation under subsection (1)(a) or of a contrary direction given by a person whilst alive, the spouse, partner, major child, parent, guardian, major brother or major sister of that person, in the specific order mentioned, may, after that 25 person's death, donate the body or any specific tissue of that person to an institution or a person contemplated in section 63.

(3) (a) The Director-General may, after the death of a person and if none of the persons contemplated in subsection (2) can be located, donate any specific tissue of that 30 person to an institution or a person contemplated in section 63.

(b) The Director-General may only donate the specific tissue if all the prescribed steps have been taken to locate the persons contemplated in subsection (2).

Human bodies, tissue, blood, blood products or gametes may be donated to prescribed institution or person

63. A human body, tissue, blood, blood products or gametes may be donated by any 35 person contemplated in section 55(a) or 62 to any prescribed institution or person for any purpose contemplated in section 56 or 64(1).

Purposes of donation of body, tissue, blood or blood products of deceased persons

64. (1) A donation in terms of section 62 may only be made for—

- (a) the purposes of the training of students in health sciences; 40
- (b) the purposes of health research;
- (c) the purposes of the advancement of health sciences;
- (d) therapeutic purposes, including the use of tissue in any living person; or
- (e) the production of a therapeutic, diagnostic or prophylactic substance.

(2) This Act does not apply to the preparation of the body of a deceased person for the 45 purposes of embalming it, whether or not such preparation involves the—

- (a) making of incisions in the body for the withdrawal of blood and the replacement thereof by a preservative; or

- (b) restoration of any disfigurement or mutilation of the body before its burial.

Revocation of donation

65. A donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document. 5

Post mortem examination of bodies

66. (1) Subject to subsection (2), a post mortem examination of the body of a deceased person may be conducted if—

- (a) the person, while alive, gave consent thereto; 10
 (b) the spouse, partner, major child, parent, guardian, major brother or major sister of the deceased, in the specific order mentioned, gave consent thereto; or
 (c) such an examination is necessary for determining the cause of death.

(2) A post mortem examination may not take place unless—

- (a) the medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, has authorised the post mortem examination in writing and in the prescribed manner; or 15
 (b) in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, has authorised the post mortem examination in writing and in the prescribed manner. 20

Removal of tissue at post-mortem examinations and obtaining of tissue by institutions and persons

67. (1) (a) The Minister may, on the written application of an institution or person requiring tissue for a purpose contemplated in section 64(1), authorise that institution or person, in writing, to obtain such tissue from a medical practitioner contemplated in subsection (3) or a person or an institution contemplated in section 63. 25

(b) The Minister may impose any condition on the institution or person to which or to whom he or she has granted an authorisation in terms of paragraph (a). 30

(c) This Act does not prevent persons or institutions from acquiring tissue in terms of the National Heritage Resources Act, 1999 (Act No. 25 of 1999), for the purposes of that Act.

(2) The medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, or, in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, may, in writing and in the prescribed manner, authorise— 35

- (a) a prescribed institution or person contemplated in section 63; or 40
 (b) an authorised institution making application therefor in writing,

to remove any specified tissue from the body concerned before burial thereof.

(3) Despite anything to the contrary in any other law, a medical practitioner who conducts a post-mortem examination in terms of—

- (a) section 3 of the Inquests Act, 1959 (Act No. 58 of 1959); or 45
 (b) section 71(1)(a) or (b),

must remove or cause to be removed from a body such tissue as may be specified in an authorisation under subsection (1) and must hand it over to the institution or person in possession of the authorisation.

(4) The removal contemplated in subsection (3) may not be effected if— 50

- (a) the removal of the tissue is likely to affect the outcome of the examination; or

- (b) the body or tissue in question has been donated or if the removal would be contrary to a direction given by the deceased before his or her death.

Regulations relating to tissue, cells, organs, blood, blood products and gametes

68. (1) The Minister may make regulations regarding—

- (a) the post mortem examination of bodies of deceased persons; 5
- (b) the preservation, use and disposal of bodies, including unclaimed bodies;
- (c) the removal of donated tissue or cells from persons, tissue or cells obtained from post mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons;
- (d) tissue transplants; 10
- (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from tissue;
- (f) the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes;
- (g) the importation and exportation of tissue, human cells, blood, blood products or gametes; 15
- (h) the withdrawal of blood from living persons and the preservation, testing, processing, supply or disposal of withdrawn or imported blood;
- (i) the administering of blood and any blood product to living persons;
- (j) the production, packaging, sealing, labelling and supplying of blood and blood products; 20
- (k) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes;
- (l) the artificial fertilisation of persons;
- (m) the appointment and functions of inspectors of anatomy and investigating officers; 25
- (n) the records and registers to be kept by persons and institutions;
- (o) the returns and reports, including extracts from registers, to be submitted to specified persons and institutions;
- (p) the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose; 30
- (q) the appointment and functions of inspectors of the national blood transfusion service and progenitor cell transplant institutions; and
- (r) any other matter relating to regulating the control and the use of human bodies, tissue, organs, gametes, blood and blood products in humans. 35

(2) The Minister, with the concurrence of the Cabinet member responsible for finance, may make regulations concerning the payment of persons or institutions in connection with procurement, storage, supply, import or export of human bodies, tissue, blood, blood products or gametes. 40

(3) The Minister may, if it is consistent with the objects of this Act and upon such conditions as the Minister may deem fit, by notice in the *Gazette* exempt any person or category of persons from any or all of the regulations made under this section.

CHAPTER 9

NATIONAL HEALTH RESEARCH AND INFORMATION

45

National Health Research Committee

69. (1) The Minister must establish a committee to be known as the National Health Research Committee.

- (2) (a) The National Health Research Committee consists of not more than 15 persons, appointed by the Minister after consultation with the National Health Council.
- (b) A person appointed in terms of paragraph (a)—
- (i) serves for a term of not more than three years and may be reappointed for one or more terms; and 5
 - (ii) ceases to be a member on resignation or if requested by the Minister for good cause to resign.
- (c) A vacancy in the National Health Research Committee must be filled by the appointment of a person for the unexpired portion of the term of office of the member in whose place the person is appointed, and in the same manner in which the member was appointed in terms of paragraph (a). 10
- (3) The National Health Research Committee must—
- (a) determine the health research to be carried out by public health authorities;
 - (b) ensure that health research agendas and research resources focus on priority health problems; 15
 - (c) develop and advise the Minister on the application and implementation of an integrated national strategy for health research; and
 - (d) coordinate the research activities of public health authorities.
- (4) The Minister must prescribe the manner in which the National Health Research Committee must conduct its affairs and the procedure to be followed at meetings of the Committee, including the manner in which decisions must be taken. 20
- (5) A member of the National Health Research Committee who is not in the full-time employment of the State must in respect of his or her service as a member be paid such remuneration as the Minister may determine with the concurrence of the Minister of Finance. 25

Identification of health research priorities

70. (1) The National Health Research Committee must identify and advise the Minister on health research priorities.
- (2) In identifying health research priorities, the National Health Research Committee must have regard to— 30
- (a) the burden of disease;
 - (b) the cost-effectiveness of interventions aimed at reducing the burden of disease;
 - (c) the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities; 35
 - (d) the health needs of vulnerable groups such as woman, older persons, children and people with disabilities; and
 - (e) the health needs of communities.

Research on or experimentation with human subjects

71. (1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted— 40
- (a) in the prescribed manner; and
 - (b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health. 45
- (2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted—
- (a) if it is in the best interests of the minor;
 - (b) in such manner and on such conditions as may be prescribed;
 - (c) with the consent of the parent or guardian of the child; and 50
 - (d) if the minor is capable of understanding, with the consent of the minor.
- (3) (a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted—
- (i) in such manner and on such conditions as may be prescribed;
 - (ii) with the consent of the Minister; 55

- (iii) with the consent of the parent or guardian of the minor; and
 - (iv) if the minor is capable of understanding, the consent of the minor.
- (b) The Minister may not give consent in circumstances where—
- (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult; 5
 - (ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors;
 - (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy; 10
 - (iv) the research or experimentation poses a significant risk to the health of the minor; or
 - (v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk. 15

National Health Research Ethics Council

72. (1) A council to be known as the National Health Research Ethics Council is hereby established.

(2) The Minister must—

(a) after consultation with the National Health Council, appoint as members of the National Health Research Ethics Council not more than 15 persons nominated by interested parties at the invitation of the Minister by notice in the *Gazette*; and 20

(b) publish the list of appointees in the *Gazette*.

(3) A member of the National Health Research Ethics Council is appointed for three years but may be reappointed for one or more further terms. 25

(4) A member of the National Health Research Ethics Council must vacate his or her office if he or she resigns or if requested by the Minister for good cause to resign.

(5) If a member of the National Health Research Ethics Council vacates office or dies, the Minister may fill the vacancy by appointing a person in accordance with subsection (2) for the unexpired portion of the term of office of his or her predecessor. 30

(6) The National Health Research Ethics Council must—

(a) determine guidelines for the functioning of health research ethics committees;

(b) register and audit health research ethics committees;

(c) set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials; 35

(d) adjudicate complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he or she has been discriminated against by a health research ethics committee;

(e) refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider; 40

(f) institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conducting of research in terms of this Act; and 45

(g) advise the national department and provincial departments on any ethical issues concerning research.

(7) For the purposes of subsection (6)(c), "clinical trials" means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment. 50

Health research ethics committees

73. (1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

(2) A health research ethics committee must—

- (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
- (b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.

Co-ordination of national health information system

74. (1) The national department must facilitate and co-ordinate the establishment, implementation and maintenance by provincial departments, district health councils, municipalities and the private health sector of health information systems at national, provincial and local levels in order to create a comprehensive national health information system.

(2) The Minister may, for the purpose of creating, maintaining or adapting databases within the national health information system contemplated in subsection (1), prescribe categories or kinds of data for submission and collection and the manner and format in which and by whom the data must be compiled or collated and must be submitted to the national department.

Provincial duties in relation to health information

75. The relevant member of the Executive Council must establish a committee for his or her province to establish, maintain, facilitate and implement the health information systems contemplated in section 74 at provincial and local level.

Duties of district health councils and municipalities

76. Every district health council and every municipality which provides a health service must establish and maintain a health information system as part of the national health information system contemplated in section 74.

CHAPTER 10**HEALTH OFFICERS AND COMPLIANCE PROCEDURES****Establishment of Inspectorate for Health Establishments**

77. (1) The relevant member of the Executive Council must establish an inspectorate in his or her province to be known as the Inspectorate for Health Establishments.

(2) An Inspectorate for Health Establishments must—

- (a) monitor and evaluate compliance with this Act by health establishments and health agencies in the province for which it is established; and
- (b) submit a quarterly report on its activities and findings to the relevant member of the Executive Council.

(3) The relevant member of the Executive Council must submit an annual report to the Minister on the activities and findings of the Inspectorate for Health Establishments established in his or her province.

Office of Standards Compliance

78. (1) The Director-General must establish an Office of Standards Compliance within the national department which must include a person who acts as ombudsperson in respect of complaints in terms of this Act.

- (2) The Office of Standards Compliance must— 5
- (a) keep the Minister informed of the quality of the health services provided throughout the Republic as measured against prescribed health standards;
 - (b) advise the Minister on norms and standards for quality in health services;
 - (c) advise the Minister on norms and standards for the certificate of need processes; 10
 - (d) recommend to the Minister any changes which should be made to the prescribed health standards;
 - (e) recommend to the Minister new systems and mechanisms to promote quality of health services;
 - (f) monitor compliance with prescribed health standards by health establish- 15
ments, health care providers, health workers and health agencies;
 - (g) monitor compliance by a health establishment, health agency, health worker and health care provider with any condition that may have been imposed on such establishment, agency, worker or provider, as the case may be, in respect of certificates of need issued in terms of this Act; 20
 - (h) report to the Minister any violation of a prescribed health standard where such violation poses an immediate and serious threat to public health and make recommendations to the Minister on the action to be taken in order to protect public health;
 - (i) prepare an annual report to the Minister concerning its findings with regard to 25
compliance with prescribed standards and with conditions imposed in respect of certificates of need;
 - (j) institute monitoring activities and processes for quality assurance in health establishments;
 - (k) provide advice to the national department and to provincial departments on 30
quality of care provided by health establishments, health agencies, health workers and health care providers;
 - (l) inspect a health establishment or health agency in order to determine levels of compliance with prescribed health standards and conditions imposed by certificates of need; and 35
 - (m) instruct a health officer or person designated by the National Commissioner of the South African Police Service in terms of section 80(3) to inspect health establishments and health agencies in order to—
 - (i) investigate any complaint, allegation or suspicion relating to the 40
observation of prescribed health standards; and
 - (ii) report to the Director-General on the findings of any investigation contemplated in subparagraph (i). 50

Inspections by Office of Standards Compliance

79. (1) The Office of Standards Compliance or its agents must inspect every health establishment and health agency at least once every three years to ensure compliance 45
with this Act, and may conduct announced or unannounced inspections of a health establishment and a health agency at any time.

(2) (a) The Office of Standards Compliance may order the total or partial closure of a health establishment or a health agency if a certificate of need was not issued in respect of that health establishment or health agency prior to any activities contemplated in 50
section 36 being undertaken.

(b) An order issued in terms of paragraph (a) must be in writing and issued to the head of the health establishment or health agency in question.

(3) If the Office for Standards Compliance orders the total or partial closure of a health establishment, the Minister must ensure, within a reasonable period from the date of such closure, that reasonable alternative and accessible health services are available to any community affected by the closure. 5

(4) The Office of Standards Compliance must issue a written notice of non-compliance to the head of a health establishment if the Office of Standards Compliance determines that—

(a) the health establishment does not comply with— 10

- (i) any provision of this Act;
- (ii) any condition imposed in a certificate of need;
- (iii) building regulations; or
- (iv) the provisions of any other law; or

(b) a health care provider or health worker associated with the health establishment is engaged in certain prescribed business or health service practices upon the basis of perverse incentives. 15

(5) A notice of non-compliance must be issued to the person determined to be responsible for any condition contemplated in subsection (3)(a) or (b) stating the nature and extent of the non-compliance and directing the appropriate corrective action to be taken within a specified period in respect of the prescribed business or health service practice or to minimise or rectify the non-compliance. 20

(6) A notice of non-compliance contemplated in subsection (3) remains in force until the relevant provision of the Act has been complied with and the Office of Standards Compliance has issued a compliance certificate in respect of that notice. 25

(7) The Office of Standards Compliance, in the event of failure to comply with the requirements of a notice of non-compliance, may—

(a) temporarily suspend the operation of, or shut down, the whole or a part of the health establishment or health agency, pending compliance with the notice of non-compliance; 30

(b) recommend to the Director-General that the certificate of need of the health establishment or health agency be withdrawn; or

(c) recommend to the Director-General that an application for the renewal of a certificate of need in respect of the health establishment or health agency be refused. 35

Appointment of health officers

80. (1) Subject to any other law—

(a) the Minister may appoint any person in the employ of the national department as a health officer of the national department;

(b) the relevant member of the Executive Council may appoint any person in the employ of the provincial department in question, as a health officer for the province in question; and 40

(c) the mayor of a metropolitan or district council may appoint any person in the employ of the council in question as a health officer for the municipality in question. 45

(2) An appointment under subsection (1) may be general or for a specific purpose.

(3) The relevant member of the Executive Council may request the National Commissioner of the South African Police Service to designate a member of the Service as a health officer for the province in question.

(4) The Minister or the relevant member of the Executive Council, as the case may be, must issue to every health officer a document in the prescribed form certifying that he or she has been appointed or designated as a health officer for the national department or provincial department in question. 50

Duty of health officers

81. A health officer must monitor and enforce compliance with this Act.

Routine inspections

82. (1) A health officer may enter any premises, excluding a private dwelling, at any reasonable time and— 5

- (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 10
- (d) take samples of any substance that is relevant to the inspection.

(2) A health officer 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 may issue a compliance notice to the person in charge of the premises if a provision of this Act has not been complied with. 15

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

(5) A health officer who removes any item other than that contemplated in subsection (1)(d) must— 20

- (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 25

83. (1) (a) 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; 30
- (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. 35

(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 head of the relevant provincial department. 40

Entry and search of premises with warrant

84. (1) A health officer accompanied by a police official may, on the authority of a warrant issued in terms of subsection (5) and subject to section 85, enter any premises specified in the warrant, including a private dwelling, and— 45

- (a) inspect, photograph, copy, test and examine any document, record, object or material, or cause it to be inspected, photographed, copied, tested and examined; 50

- (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 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 5
- (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 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, 10
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 15
- (c) render such reasonable assistance as the health officer 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 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. 20
- (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 25
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.
- (7) A warrant issued in terms of this section—
- (a) remains in force until— 30
- (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, 35
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 under this section. 40

Identification prior to entry, and resistance against entry

85. (1) A health officer 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 in question—
- (a) audibly announce that he or she is authorised to enter the premises and 45
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 must— 50
- (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 to that person.

(3) A health officer 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. 5

(4) Before using force, the health officer 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 accompanied by a police official may without a warrant exercise any power referred to in section 84(1) if— 10

(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. 15

Disposal of items seized by health officer

87. (1) The health officer 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. 20

(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.

Miscellaneous provisions relating to health officers, inspectors and compliance procedures 25

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— 30

(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.

Offences 35

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

(a) obstructs or hinders a health officer who is performing a function under this Act;

(b) refuses to provide a health officer with such information as that person is required to provide under this Act; 40

(c) knowingly gives false or misleading information to a health officer;

(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; 45

- (f) fails to comply with a compliance notice issued to him or her by a health officer 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— 5
- (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) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment. 10

CHAPTER 11

REGULATIONS

Regulations

15

90. (1) The Minister, after consultation with the National Health Council, may make regulations regarding—
- (a) anything which may or must be prescribed in terms of this Act;
- (b) the fees to be paid to public health establishments for health services rendered;
- (c) the norms and standards for specified types of protective clothing and the use, cleaning and disposal of such clothing; 20
- (d) the development of an essential drugs list and medical and other assistive devices list;
- (e) human resource development;
- (f) co-operation and interaction between private health care providers and private health establishments on the one hand and public health care providers and public health establishments on the other; 25
- (g) returns, registers, reports, records, documents and forms to be completed and kept by the national department, provincial departments, district health councils, health care providers, private health establishments and public health establishments; 30
- (h) the functions of persons who render voluntary, charitable or similar services in connection with a public health establishment;
- (i) the rendering of forensic pathology, forensic medicine and related laboratory services, including the provision of medico-legal mortuaries and medico-legal services; 35
- (j) communicable diseases;
- (k) notifiable medical conditions;
- (l) rehabilitation;
- (m) emergency medical services and emergency medical treatment, both within and outside of health establishments; 40
- (n) health nuisances and medical waste;
- (o) the import and export of pathogenic micro-organisms;
- (p) health laboratory services, including—
- (i) the classification, accreditation and licensing of health laboratories; and 45
- (ii) setting, monitoring and enforcing quality control standards applicable to health laboratories;
- (q) non-communicable diseases;
- (r) health technology;
- (s) health research; 50
- (t) the national health information system contemplated in section 74;
- (u) the processes and procedures to be implemented by the Director-General in order to obtain prescribed information from stakeholders relating to health

- financing, the pricing of health services, business practices within or involving health establishments, health agencies, health workers and health care providers, and the formats and extent of publication of various types of information in the public interest and for the purpose of improving access to and the effective and efficient utilisation of health services; 5
- (v) the processes of determination and publication by the Director-General of one or more reference price lists for services rendered, procedures performed and consumable and disposable items utilised by categories of health establishments, health care providers or health workers in the private health sector which may be used— 10
- (i) by a medical scheme as a reference to determine its own benefits; and
- (ii) by health establishments, health care providers or health workers in the private health sector as a reference to determine their own fees, but which are not mandatory; and
- (w) generally, any other matter which it is necessary or expedient to prescribe in order to implement or administer this Act. 15
- (2) The Minister, subject to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), and after consultation with the National Health Research Ethics Council, may make regulations regarding research on human subjects.
- (3) The Minister may, in any regulation made under this Act— 20
- (a) designate as authoritative any methodology, procedure, practice or standard that is recognised as authoritative by internationally recognised health bodies within the relevant profession; and
- (b) require any person or body to comply with the designated methodology, procedure, practice or standard. 25
- (4) (a) The Minister must publish all regulations proposed to be made under this Act in the *Gazette* for comment at least three months before the date contemplated for their commencement.
- (b) If the Minister alters the draft regulations, as a result of any comment, he or she need not publish those alterations before making the regulations. 30
- (c) The Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without the consultation contemplated in paragraph (a).

CHAPTER 12

GENERAL PROVISIONS 35

Minister may appoint committees

91. (1) The Minister may, after consultation with the National Health Council, establish such number of advisory and technical committees as may be necessary to achieve the objects of this Act.
- (2) When establishing an advisory or technical committee, the Minister may 40 determine by notice in the *Gazette*—
- (a) its composition, functions and working procedure;
- (b) in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and
- (c) any incidental matters relating to that advisory or technical committee. 45

Assignment of duties and delegation of powers

92. Subject to the Public Finance Management Act (Act No. 1 of 1999)—

- (a) the Minister may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations, to—
 - (i) any person in the employ of the State; or
 - (ii) any council, board or committee established in terms of this Act;
- (b) the relevant member of the Executive Council may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations, or assigned or delegated to him or her by the Minister, to any officer in the relevant provincial department or any council, board or committee established in terms of this Act;
- (c) the Director-General may assign any duty and delegate any power imposed or conferred upon him or her by this Act to any official in the national department; and
- (d) the head of a provincial department may assign any duty and delegate any power imposed or conferred upon him or her in terms of this Act to any official of that provincial department.

Repeal of laws, and savings

93. (1) Subject to this section, the laws mentioned in the second column of the Schedule are hereby repealed to the extent set out in the third column of the Schedule.

(2) Anything done before the commencement of this Act under a provision of a law repealed by subsection (1) and which could have been done under a provision of this Act must be regarded as having been done under the corresponding provision of this Act.

(3) The Minister may prescribe such further transitional arrangements as may be necessary to effect a smooth transition between the laws referred to in the Schedule and this Act.

Short title and commencement

94. This Act is called the National Health Act, 2003, and takes effect on a date fixed by the President by proclamation in the *Gazette*.

SCHEDULE**LAWS REPEALED***(Section 93)*

No. and year of Act	Short title	Extent of repeal
Act No. 63 of 1977	Health Act, 1977	The whole
Act No. 18 of 1979	Health Amendment Act, 1979	The whole
Act No. 33 of 1981	Health Amendment Act, 1981	The whole
Act No. 37 of 1982	Health Amendment Act, 1982	The whole
Act No. 21 of 1983	Health Amendment Act, 1983	The whole
Act No. 65 of 1983	Human Tissue Act, 1983	The whole
Act No. 2 of 1984	Health Amendment Act, 1984	The whole
Act No. 106 of 1984	Human Tissue Amendment Act, 1984	The whole
Act No. 70 of 1985	Health Amendment Act, 1985	The whole
Act No. 51 of 1989	Human Tissue Amendment Act, 1989	The whole
Act No. 16 of 1990	National Policy for Health Act, 1990	The whole
Act No. 86 of 1993	Academic Health Centres Act, 1993	The whole
Act No. 118 of 1993	Health and Welfare Matters Amendment Act, 1993	Sections 1, 2, 4, 5, 6, 7, 8, 9 and 10