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## CHAPTER 7

### ACADEMIC HEALTH SERVICE COMPLEXES

#### 60. ESTABLISHMENT OF ACADEMIC HEALTH SERVICE COMPLEXES

- (1) The *Minister* may establish *academic health service complexes*, with the concurrence of
  - (a) the member of Cabinet responsible for Education;
  - (b) the *relevant Member of the Executive Council*;
  - (c) relevant educational institutions; and
  - (d) the relevant hospital boards.
- (2) The functions and responsibilities of *academic health service complexes* shall be to -
  - (a) co-ordinate the education and training of students at undergraduate and post-graduate levels in respect of the health occupations for which they have enrolled;
  - (b) promote research and continuing education;
  - (c) provide appropriate facilities for education, training and research; and
  - (d) to provide health care services as *prescribed* for each of the constituent *health establishments*.

#### 61. ESTABLISHMENT, COMPOSITION AND DUTIES OF NATIONAL COUNCIL FOR ACADEMIC HEALTH SERVICE COMPLEXES

- (1) The National Council for Academic Health Service Complexes is hereby established.
- (2) The National Council for Academic Health Service Complexes, shall consist of -
  - (a) a chairperson appointed by the *Minister*;
  - (b) the *Director-General*;

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- (c) representative appointed by Minister of Education;
  - (d) representative appointed by the Minister of Arts, Culture, Science and Technology;
  - (e) two representatives from the *academic health service complex* co-ordinating committee;
  - (f) one representative from each *provincial department*;
  - (g) three *persons* from Health Statutory Councils; and
  - (h) one *person* from health related statutory research institutes.
- (3) The functions and responsibilities of the National Council for Academic Health Service Complexes are -
- (a) to consider any matter relating to the functions of any *academic health service complex* and make recommendations to the *Minister* and the *National Health Authority*;
  - (b) to promote co-operation between health authorities, educational and research institutions in the *academic health service complex*;
  - (c) to determine the area for which each *academic health service complex* will take primary responsibility for providing academic resources and continuing health professional education, and for monitoring and promoting academic and professional standards; and
  - (d) to perform any function the Council considers necessary or expedient for the achievement of the objectives of *this Act*.
- (4) The National Council for Academic Health Service Complexes may -
- (a) determine its own procedures for conducting its business;
  - (b) establish one or more committees to assist it in the co-ordination of academic health service complexes and performance of its functions; and

- (c) determine the composition of each committee, which may include *persons* who are not members of the Council.

**62. DEVELOPMENT AND PROVISION OF HUMAN RESOURCES IN THE NATIONAL HEALTH SYSTEM**

The *National Health Authority* must develop policy and guidelines for and monitor the production, provision, distribution, development, management, and utilisation of human resources within the health system.

**63. MAXIMISING THE SERVICES OF HEALTH CARE PROVIDERS**

The *Minister*, with the concurrence of the *National Health Authority*, must determine guidelines to enable the *provincial departments* and *district health authorities* to implement programmes for the appropriate distribution of *health care providers*.

**64. PRIMARY HEALTH CARE AND REFERRAL TEAMS**

Provincial legislation must provide for the establishment of primary health care and referral teams.

## **CHAPTER 8**

### **CONTROL OF THE USE OF TISSUE AND ORGANS IN HUMANS**

**65. NATIONAL BLOOD TRANSFUSION SERVICE**

- (1) A National Blood Transfusion Service is hereby established.
- (2) The composition of the National Blood Transfusion Service will be determined by regulation by the *Minister*.
- (3) The operation and functioning of the National Blood Transfusion Service will be in terms of national health policy.

- (4) The National Blood Transfusion Service may establish provincial units that will exercise maximal management autonomy.
- (5) Notwithstanding the provisions of subsection (3) above, the executive authority of the regional blood transfusion services will reside with the National Blood Transfusion Service.
- (6) No person other than the National Blood Transfusion Service must render a blood transfusion service in the Republic of South Africa.
- (7) Any person who contravenes the provisions of subsection (5) above commits an offence.
- (8) The National Blood Transfusion Service is a non-profit organisation.

#### **66. DESIGNATION OF AUTHORISED INSTITUTION**

- (1) The **Minister** may, by notice in the *Gazette*, designate any institution which is not an institution referred to in section 75 as an **authorised institution** for purposes of empowering the institution to -
  - (a) acquire, use and supply bodies of deceased persons for any of the purposes referred to in section 76;
  - (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 76 or 68 , as the case may be; and
  - (c) supply any tissue preserved by it to an institution or person referred to in section 75 for any of the purposes referred to in section 76 or 68.
- (2) The **Minister** may impose conditions on authorised institutions and may vary or withdraw conditions applicable to any **authorised institution**.

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**67. CONSENT FOR THE REMOVAL OF TISSUE, BLOOD OR GAMETES FROM LIVING PERSONS**

A person may not remove *tissue*, blood or *gametes* from the body of another living person for a purpose referred to in section 68 unless the removal is effected -

- (a) in accordance with the *prescribed* conditions; and
- (b) with written consent thereto granted in the prescribed manner.

**68. PURPOSES FOR WHICH TISSUE, BLOOD OR GAMETES OF LIVING PERSONS MAY BE USED**

- (1) Subject to the provisions of this Chapter and unless otherwise *prescribed*, a person may use *tissue*, blood or *gametes* removed or withdrawn from a living person only for medical or dental purposes.
- (2) *Tissue*, blood or *gametes* of the following types or persons may not be used for the purposes that are contemplated in section 76:
  - (a) *tissue*, blood or *gamete* of a person who is mentally ill within the meaning of the Mental Health Act, 1973 (Act No. 18 of 1973);
  - (b) *tissue* which is not replaceable by natural processes and which has been removed from a person younger than eighteen years;
  - (c) a *gamete* removed from a person younger than eighteen years; or
  - (d) placenta, foetal *tissue* and umbilical cord(s),except with the consent of the *Minister* and subject to any condition mentioned in the consent.

**69. PROHIBITION OF THE TRANSPLANT OF GONADS**

- (1) No person may transplant a gonad removed from a deceased or living person to another living person where that transplant could result in procreation, without the prior written authorisation of the *Minister* for the transplant.

- (2) Any person who contravenes the provisions of subsection (1) commits an offence.

#### **70. REQUIREMENTS WITH REGARD TO TISSUE TRANSPLANTS**

- (1) A person may not remove *tissue* from a living person for transplantation to another living person or carry out such transplantation except -
- (a) in a *hospital, health establishment* or *authorised institution*; and
  - (b) with the written authority of a medical practitioner responsible for clinical services in that *hospital, health establishment* or *authorised institution* concerned.
- (2) A medical practitioner contemplated in subsection (1)(b) may not participate in a transplant for which she or he has granted authorisation in terms of that subsection.

#### **71. CONTROL OF REMOVAL AND USE OF TISSUE OR BLOOD**

- (1) Only a registered medical practitioner or dentist may, for the purposes of this Chapter, remove any *tissue* from a living person and/or use or transplant *tissue* so removed on another living person.
- (2) Only a registered medical practitioner, dentist or a person acting under the supervision of the medical practitioner or dentist, may for purposes of this Chapter administer blood or a blood product to a living *person*.

#### **72. PAYMENT IN CONNECTION WITH THE IMPORTATION, ACQUISITION, OR SUPPLY OF TISSUE, BLOOD, BLOOD PRODUCTS OR GAMETES**

- (1) No person except -
- (a) a person or institution referred to in section 74, an *authorised institution* or, in the case of *tissue* or *gametes* imported in terms of the regulations, the importer concerned, may receive payment in respect of the importation, acquisition or supply of any *tissue* or *gamete* for or to another person for any of the purposes referred to in section 67 or 75;

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- (b) a person or institution referred to in section 74, an **authorised institution** or person may receive any payment in respect of the importation or acquisition for or the supply to another person of blood or a blood product.
- (2) The provisions of this section do not prevent a registered medical practitioner or registered dentist from receiving remuneration for professional services rendered by him or her to any person.
- (3) It is an offence for a person who has donated **tissue, gametes** or blood to receive any form of financial reward for such a **donation**, except for the reimbursement of costs incurred by him or her to provide such **donation**

### 73. **HUMAN ORGANS AS NATIONAL ASSETS**

- (1) Human **organs** obtained from deceased persons for the purpose of transplantation, treatment, or medical or dental training and research are national assets.
- (2) It is an offence to charge a fee in relation to the **donation** of human **organs**.

### 74. **DONATION OF HUMAN BODIES AND TISSUE**

- (1) A person who is competent to make a will may in the will, or in a document signed by him or her and at least two competent witnesses, or in a oral statement made in the presence of at least two competent witnesses -
- (a) donate his or her body or any specific **tissue** thereof, to be used after death for any medical and/or dental purposes in terms of this Act ; or
- (b) give consent to a post-mortem examination of his or her body for any of those purposes; and
- (c) nominate an institution or person as donee.
- (2) Subsection (1)(c) does not apply in respect of the **donation** of an **organ** which constitutes a national asset and the donee of such an **organ** must be determined in terms of subsection (4) below.

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- (3) In the absence of a *donation* under subsection (1)(a) or of a contrary direction given by that person, the spouse, major child, parent, guardian, major brother or major sister of that person may, after that person's death, donate the body or any specific *tissue* of that person to an institution or person in terms of this Act.
- (4) The *Director-General* may, after the death of a person, donate any specific *tissue* of that person to a specific institution or person if -
- (a) none of the persons referred to in subsection (3) can be located; and
  - (b) the *Director-General* is satisfied that all reasonable steps have been taken to locate those persons.

#### **75. INSTITUTIONS TO WHICH AND PERSONS TO WHOM HUMAN BODIES OR TISSUE MAY BE DONATED**

- (1) A human body, *tissue*, blood or *gametes* may be donated, in terms of section 73, to any of the prescribed institutions or persons.
- (2) A person may only remove and allocate *organs* in accordance with procedures *prescribed* by the *Minister*.
- (3) A person may not transplant an *organ* into another person who is not a citizen or permanent resident of the Republic of South Africa without written authority from the *Minister*.
- (4) The *Minister* must determine -
- (a) criteria for the approval of *organ* transplant facilities; and
  - (b) procedural measures to be applied for such approval.

#### **76. PURPOSES OF DONATION**

A person may donate a human body or specific *tissue* to a person or institution only for the purposes of -

- (a) medical or dental training;

- (b) research;
- (c) the advancement of medicine or dentistry; or
- (d) therapeutic purposes, including the *use of tissue* on any living person or persons or for the production of a therapeutic, diagnostic or prophylactic substance.

#### **77. REVOCATION OF DONATION**

A donor may 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.

#### **78. POST-MORTEM EXAMINATION OF BODIES**

A post-mortem examination of a deceased person may be conducted before the burial of that person if

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

#### **79. REMOVAL OF TISSUE AT POST-MORTEM EXAMINATIONS AND OBTAINING OF TISSUE BY INSTITUTIONS AND PERSONS**

- (1) The *Minister* may, on the written application of an institution or person requiring *tissue* for a purpose referred to in section 76, authorise that institution or person in writing to obtain such *tissue* from a medical practitioner referred to in section 71 or an institution.
- (2) When granting an authorisation in terms of subsection (1), the *Minister* may prescribe conditions for which the *tissue* that is so obtained may be used.

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- (3) Notwithstanding any law, a medical practitioner who is to conduct a post-mortem examination in terms of -
- (a) section 3 of the Inquests Act, 1959 (Act No. 58 of 1959); or
  - (b) section 78 of this Act;
- may remove or cause to be removed from a body *tissue* stated in an authority referred to in subsection (1) and shall hand it over to the person in possession of the authority
- (4) Subsection (3) does not preclude the removal of eyes or eye *tissue* from a body by an eye bank technician.

#### **80. REGULATIONS RELATING TO TISSUE, ORGANS, BLOOD AND GAMETES**

- (1) The *Minister* may make regulations regarding the following -
- (a) the post-mortem examination of bodies of deceased persons;
  - (b) the preservation, *use* and disposal of unclaimed bodies of deceased persons;
  - (c) the removal of donated *tissue* from deceased persons, *tissue* obtained from post-mortem examinations, and the procurement, storage and allocation of *tissue* by institutions and persons;
  - (d) *tissue* transplant;
  - (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from *tissue*;
  - (f) the sale and supply of human *tissue*, blood, blood products or *gametes*;
  - (g) the importation and exportation of *tissue*, blood, blood products or *gametes*;
  - (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 products;

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- (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 fertilization of persons;
  - (m) the appointment, powers and functions of inspectors of anatomy and investigating officers;
  - (n) the 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; and
  - (p) any other matter related to regulating the control and the use of *tissue, organs, gametes*, blood and blood products in humans.
- (2) The *Minister*, with the concurrence of the member of the Cabinet responsible for State Expenditure, may make regulations concerning the payment of public money to persons or institutions in connection with procurement, storage, supply, import or export of human *tissue*, blood, blood products or *gametes*.

## **CHAPTER 9**

### **HEALTH SURVEILLANCE, RESEARCH AND INFORMATION**

#### **81. THE ESSENTIAL NATIONAL HEALTH RESEARCH COMMITTEE**

- (1) The Essential National *Health Research* Committee is established.
- (2) The Committee shall be composed of persons appointed by the *Minister*, including but not limited to:
  - (a) 3 research managers;
  - (b) 3 basic researchers;
  - (c) 3 clinical researchers;
  - (d) 3 community researchers;

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- (e) 2 policy analysts from the *national department* and 2 representatives of *provincial departments* of health, 3 policy makers from other relevant government departments and 2 service providers; and
  - (f) 2 private sector representatives with a special interest in or knowledge of research.
- (3) The functions of this Committee include -
- (a) the determination of *health research* to be carried out by public health authorities;
  - (b) directing *health research* agenda and research resources to focus on priority health problems;
  - (c) the development and application of an integrated national strategy for *health research*; and
  - (d) the co-ordination of research activities of public health authorities.
- (4) The *Minister* must *prescribe* -
- (a) procedures for conducting the Committee's business;
  - (b) the procedure for appointing and terminating the services of persons referred to in subsection (2) and their terms, conditions of service, remuneration and allowances.

## 82. DETERMINATION OF HEALTH RESEARCH PRIORITIES

The *Essential National Health Research Committee*, in determining *health research* priorities, must have regard, amongst other things, to –

- (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 intervention at the level closest to the affected communities; and
- (d) the health needs of communities.

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### 83. **RESEARCH ON HUMAN SUBJECTS**

Notwithstanding the provisions of any other law, research on human subjects may only be carried out as determined by the **Minister**, with the written consent of the subject, after he or she has been informed of the objects of the experimentation and the possible positive or negative consequences on his or her health, provided in the case of a minor there is compliance with section 39 (4) of the Child Care Act, 1983 (Act No.74 of 1983).

### 84. **ESTABLISHMENT, DUTIES AND COMPOSITION OF THE NATIONAL HEALTH ETHICS COUNCIL**

- (1) The National Health Ethics Council is established.
- (2) The **Minister** shall, in consultation with the **National Health Authority**, appoint the members of the National Health Ethics Council from a list of nominations and publish the list of appointees in the *Gazette*.
- (3) The functions of the National Health Ethics Council shall include -
  - (a) the provision of guidelines for the functioning of health ethics committees;
  - (b) registration and auditing of health ethics committees for human and animal research;
  - (c) setting of norms and standards for conducting research on humans and animals, including *clinical trials*;
  - (d) adjudicating instances of complaints about the functioning of health ethics committees;
  - (e) hearing complaints by researchers who believe that they have been discriminated against by a health ethics committee;
  - (f) instituting disciplinary action against those found to be in violation of acceptable ethical research practice;
  - (g) providing advice to the *national and provincial departments* on ethical issues; and

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- (h) any other activities that may be required to maintain and improve ethical practice in research.
  - (4) The National Health Ethics Council shall be appointed by the *Minister* from a list of nominations and composed of the following -
    - (a) 3 persons with distinguished record of research ethics;
    - (b) 3 persons involved in ethics education;
    - (c) 3 community representatives;
    - (d) 3 persons from the public health sector;
    - (e) 2 persons from the private health sector; and
    - (f) 1 person representing the Medicines Control Council.
  - (5) The National Health Ethics Council shall be funded through *prescribed* registration fees paid by Health Ethics Committees referred to in section 85 below.

#### 85. *HEALTH ETHICS COMMITTEES*

- (1) Research institutions and *health establishments* at which *health research* is conducted, shall establish or have access to health ethics committees which shall register with the National Health Ethics Council.
- (2) The functions of the Health Ethics Committee shall include:
  - (a) reviewing research proposals and protocols to ensure that research conducted will promote health, prevent disease and *disability* and cure disease; and
  - (b) granting approval in instances where research proposal and protocol meet the ethical standards of the committee.

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**86. CO-ORDINATION OF NATIONAL HEALTH INFORMATION SYSTEM**

The *national department* shall co-ordinate the establishment and maintenance by *provincial departments*, district health authorities, municipalities and the private health sector of a comprehensive national health information system;

**87. ESTABLISHMENT OF NATIONAL HEALTH INFORMATION SYSTEM COMMITTEE**

- (1) A National Health Information System Committee is established.
- (2) The *Minister*, with the concurrence of the *National Health Authority* shall appoint members of the committee.
- (3) The functions of the committee shall include the investigation and making of recommendations when requested to do so by the *National Health Authority* on any matter relating to the development, implementation and review of the national health system.
- (4) The size, period of office and functioning of the committee shall be determined by the *Minister*.

**88. PROVINCIAL FUNCTIONS IN RELATION TO HEALTH INFORMATION**

The *relevant Member of the Executive Council* of each province shall establish a committee for her or his province whose duties shall include the facilitation and implementation of the national health information system at provincial and district level.

**89. DUTIES OF DISTRICT HEALTH AUTHORITIES AND MUNICIPALITIES**

District health authorities and *municipalities* which render health services must establish and maintain a health information system in connection with matters within the scope of their functions.