

No. R. 268

1 April 2011

NATIONAL HEALTH ACT, 2003**REGULATIONS REGARDING THE GENERAL CONTROL OF HUMAN BODIES,
TISSUE, BLOOD, BLOOD PRODUCTS AND GAMETES**

The Minister of Health intends, in terms of section 90(1), read with section 68(1) of the National Health Act 2003 (Act No. 61 of 2003), and after consultation with the National Health Council, to make the regulations in the Schedule.

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

SCHEDULE**CHAPTER 1*****Definitions***

1. In these regulations any word or expression to which a meaning has been assigned in the act shall have such meaning and, unless the context otherwise indicates-

"the Act" means the National Health Act, 2003 (Act No 61 of 2003)

"artificial fertilisation" means the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction, including –

- (a) the bringing together outside the human body of a male and female gamete or gametes with a view to placing the product of a union of such gametes in the womb of a female person; or
- (b) the placing of the product of a union of a male and a female gamete or gametes which have been brought together outside the human body, in the womb of a female person;

"bury" means inter or cremate or dispose of in any other lawful manner;

"competent person" means –

- (a) in the case of the intravenous or intra-arterial withdrawal of blood, a person registered in terms of the Health Professions Act, 1974 or the Nursing Act, 2005 or
- (b) in the case of a finger prick for the withdrawal of a drop of blood for testing purposes, a person authorised in terms of the Regulations Relating to the Withdrawal of Blood From a Living Person for Testing.

"competent witness" means a person who is 14 years or over and who is competent to give evidence in a court of law;

"dentist" means a person registered as a dentist in terms of the Health Professions Act, 1974 (Act No 56 of 1974);

"donation" means the donation of a human body or any specific tissue in accordance with the Act;

"donee" means an institution or person to which or to whom a human body or tissue has been donated;

“inspector of blood transfusion services” means an inspector of blood transfusion services appointed as such under the Regulations Relating to Blood and Blood Products;

“investigating officer” means a person appointed as an investigating officer under regulation 21;

“medical practitioner” means a person registered as a medical practitioner in terms of the Health Professions Act, 1974 (Act No 56 of 1974);

“national blood transfusion service” means the organisation established in terms of section 53;

“section” means a section of the Act; and

“tissue bank” means an organisation, institution or person registered in terms of the Regulations Relating to Tissue Banks.

CHAPTER 2

THE PROCUREMENT AND USE OF TISSUE, BLOOD AND GAMETES OF LIVING PERSONS

Consent for the removal of tissue, blood and gametes from living persons

2. A person may not remove tissue, blood or gametes from the body of another living person for a purpose referred to in section 54 and regulation 3 unless written consent thereto has been granted as follows—
 - (a) where such person is older than 18 years, by that person;
 - (b) where such person is younger than 18 years, by the parents or guardians of that person: and

- (c) paragraph (b) is not applicable to gametes donors who shall never be younger than 18 years.

Purposes for which tissue, blood or gametes of living persons may be used and the withdrawal of blood

- 3. (1) Tissue, blood and gametes removed or withdrawn from living persons may only be used for medical and dental purposes, including –
 - (a) in case of such tissue, the transplanting thereof in the body of another living person or for the production of a therapeutic, diagnostic or prophylactic substance;
 - (b) in the case of such blood, for testing, the administering thereof to another living person or the production of a blood product; and
 - (c) in the case of such gamete, the artificial fertilisation of another person.
- (2) (a) No person, except a competent person, may for the purposes of this regulation, withdraw any blood or blood product from the body of a living person.

Institutions to which and persons to whom human tissue, blood, blood product and gametes may be donated

- 4. Specific tissue, blood, blood product or gametes from a living person may be donated to any of the following institutions or persons –
 - (a) in the case of tissue -
 - (i) a hospital;
 - (ii) a university or University of Technology ;
 - (iii) an authorised institution;

- (iv) a medical practitioner;
 - (v) a dentist;
 - (vi) a tissue bank or any person who requires therapy in which the tissue concerned can be used;
- (b) in the case of blood or blood product, to the national blood transfusion service or an authorised institution;
- (c) in the case of gametes, to any person contemplated in the Regulations Relating to Artificial Fertilisation of Persons;

CHAPTER 3

THE PROCUREMENT AND USE OF HUMAN BODIES AND TISSUE OF DECEASED PERSONS

Donations

5. (1) A donation that does not have a specific institution as donee, the institution in the appropriate category which is nearest to the place where the body is kept of the person whose body or tissue has been so donated, shall be deemed to be the donee.
- (2) If a donation has been made to a specific donee who is not within easy reach at the time and place of the death of the person whose body or any specific tissue thereof was so donated the institution in the appropriate category which is nearest to that place shall be deemed to be the donee.
- 6 If a person has made conflicting donations, effect shall be given to the donation which was last made: Provided that if such a person had first donated her or his entire body to one donee and thereafter donated any specific tissue thereof to

another donee, the donation of her or his entire body shall be deemed to be a donation of the remainder of her or his body.

Purposes of donation

7. (1) The purposes of a donation need not be expressly stated, but a donation shall be of no force and effect if made for any purpose other than a purpose referred to in section 64(1).
- (3) An institution, medical practitioner, dentist or person to whom specific tissue has been supplied may use the tissue only for the purposes referred to in section 64).

Removal of donated tissue

8. (1) Except in the case of a donation of the entire body, a donee shall have a period of 24 hours after the death of the person of whom any specific tissue was donated within which she or he may remove or cause to be removed the tissue so donated.
- (2) After expiry of the period referred to in subregulation (1) and irrespective of whether or not the donee has so removed that tissue or caused to be removed, the body may be claimed for burial or otherwise by the spouse, partner or any relative of the deceased or by any other person who is otherwise entitled thereto.
- (3) Authority under section 67) for the removal of eye tissue in terms of subregulation (1) and (2) shall not be required if the medical practitioner effecting the removal or under whose supervision the removal is effected, is satisfied that –
- (i) the tissue concerned has been donated in accordance with section 62;

- (ii) the body concerned is no longer required for the purpose of an examination and
- (iii) the removal of the tissue concerned is necessary for any of the purposes referred to in section 64.

Establishment of death

9. The death of a person concerned shall be established by at least two medical practitioners, one of whom shall have been practising as a medical practitioner for at least five years after the date on which she or he was registered as a medical practitioner, and none of those medical practitioners shall transplant tissue removed from that person into a living person or take part in such transplantation: Provided that where the tissue concerned is eye tissue, the death of the person from whom the tissue is removed shall be deemed to have been established by the issuing of a certificate of death in terms of the relevant law by a medical practitioner in respect of that person.

Disposal of unclaimed bodies of deceased persons

10. (1) The body of a deceased person that is not buried, or claimed for burial within 30 days after the death of that person by the spouse, partner or any relative or *bona fide* friend of the deceased, shall be at the disposal of the inspector of anatomy in whose area the body is.
- (2) Subject to any order by an inspector of anatomy, the person in charge of an institution or any other person in whose care the body referred to in subregulation (1) is, shall not hand it over to any person other than a spouse, partner, relative or friend, referred to in subregulation (1), who is known to her or him, unless the person requesting it produces to her or him an order of a magistrate authorising the handing over of the body to that person.

- (3) An inspector of anatomy shall not issue an order referred to in subregulation (2) unless the person applying for the order undertakes to pay the cost of the burial of the body concerned, and the magistrate is satisfied that that person is the spouse, partner or a relative or *bona fide* friend of the deceased.

Notice to the inspector of anatomy

11. (1) If a body has not within 30 days after the death of the deceased been buried, or claimed for burial by a spouse, partner, relative or friend, the person in charge of the institution concerned, or any other person in whose care the body is, shall forthwith direct a notice to that effect, stating the particulars in respect of the body, to the inspector of anatomy concerned.
- (2) If the notice referred to in subregulation (1) has not been directed to the inspector of anatomy in writing, it shall be repeated in writing within 30 days after the death of the deceased.

Handing over of bodies to certain institutions

12. (1) An inspector of anatomy may on receipt of a notice contemplated in regulation 11(1) by written order direct that the body concerned be handed over to a specific institution situated within the area of the inspector of anatomy concerned, or such an institution nearest to where the body is.
- (2) (a) An inspector of anatomy shall not issue an order contemplated in subregulation (1) if she or he suspects on reasonable grounds that the deceased at the time of her or his death was suffering from a disease specified by the Director-General in a notice given by her

or him for the purpose of this regulation to every inspector of anatomy.

- (b) The Director-General may at any time amend or withdraw such a notice.
- (3) If no order under subregulation (1) is issued within 2 days after the receipt of a notice contemplated in regulation 11(1), the body concerned shall no longer be at the disposal of the inspector of anatomy concerned.

Bodies to be preserved for certain period before use

- 13. (1) The person in charge of an institution to which a body has been handed over shall keep and preserve that body for a period of not less than 14 days before it may be used: Provided that, if the said person deems it advisable, any tissue of such a body may be removed and preserved separately.
- (2) The provisions of regulation 10(2) and (3) shall also apply if any person within the period referred to in subregulation (1) requests the person in charge of the institution concerned to hand over to her or him the body which is being kept and preserved in terms of subregulation (1).

Granting of authority

- 14. (1) No authority shall be granted for conducting a post-mortem examination or the removal of tissue unless the medical practitioner concerned is satisfied, except in a case where application is made for conducting a post-mortem examination for a purpose referred to in section 66 that-
 - (a) the body or tissue concerned was donated;

- (b) the body concerned is no longer required for the purpose of an examination.
 - (c) the removal of the tissue concerned or the post-mortem examination concerned is necessary for any of the purposes referred to in section 64(1) or 66(c).
- (2) Notwithstanding the provisions of subregulation (1)(b)(i), authority may be granted for the removal, of any specific tissue from a body which is required for the purpose of an examination, if the medical practitioner who is to conduct the examination concerned, certifies that she or he is satisfied that the removal of that tissue will in no way affect the outcome of that examination and that she or he has no objection to the removal of that tissue.
- (3) If a person who has died has in her or his will or in a document donated tissue of her or his body, a medical practitioner may act upon that will or document if on the face of it appears to be legally valid.

Disposal of bodies and tissue

15. An institution which or a person who has obtained a human body or tissue, and no longer requires such body or tissue or any part thereof shall –
- (a) bury or cause to bury such body or tissue or such part thereof; and
 - (b) enter in the register referred to in regulation 16, the date, place and manner of such burial.

Registers

16. (1) A register shall be kept by –
- (a) a medical practitioner –

- (i) who has removed eye tissue or under whose supervision such removal was effected;
 - (ii) who has removed or caused to be removed tissue and who has handed over such tissue to the holder of an authority; or
 - (iii) who has granted an authority in terms of section 66 and 67; or
 - (b) an institution which or person who receives a body or specific tissue donated in terms of section 62; and
 - (c) an institution –
 - (i) which supplied tissue; or
 - (ii) to which a body has been handed over.
- (2) The following particulars shall be recorded in a register –
- (i) The name, population group, sex and age at the time of death of the deceased concerned;
 - (ii) the nature and quantity of the tissue concerned;
 - (iii) the name and address of the institution or person to which or to whom the tissue concerned was donated; and
 - (iv) the date of removal of the tissue concerned from the body of the deceased; and
 - (v) the nature of the donation and, if the body as a whole was not donated, particulars of the specific tissue donated;
 - (vi) the date of receipt of the body concerned; and
 - (vii) the date of the order referred to in regulation 12(1).
- (3) A register referred to in subregulation (1) –

- (a) shall, when not in use, be stored in a strong-room or, where a strong-room is not readily available, in a place where it is reasonably protected against fire, theft or destruction; and
- (b) shall, except where an inspector of anatomy otherwise determines in writing, be retained for a minimum period of at least five years after the last entry in such register.

CHAPTER 4

HANDLING, CONVEYANCE, IMPORT, EXPORT AND DISINTERMENT OF HUMAN BODIES

Handling, conveyance and burial of bodies

17. (1) The body of a person who suffered from anthrax, cholera, a haemorrhagic fever of Africa, hepatitis B, rabies, meningococcaemia, plague, poliomyelitis or typhoid fever at the time of his or her death may not be conveyed in public in any way unless -
- (a) such a body is sealed in an airtight container and placed in a sturdy non-transparent sealed coffin and the total surface of the body is covered with a 5 cm layer of wood sawdust or other absorbent material which is treated with a disinfectant and an authorised medical officer or an environmental health practitioner in the employ of the state or local authority concerned, or any medical practitioner specifically so authorised by the local authority concerned declares in writing that in his or her opinion the conveyance of the body will not constitute a health hazard; and
 - (b) such declaration accompanies the body at all times during the conveyance and up to the burial.

- (2) The declaration referred to in subregulation (1) shall be shown to a health officer on demand, by the person responsible for the conveyance of the body.
- (3) No person shall damage a container referred to in subregulation (1) (a), or open such container or remove the body from the container or come into direct contact with the body after it has been sealed without prior approval from an officer or practitioner referred to in subregulation (1) (a).
- (4) No person shall convey a body –
 - (a) on public transport unless the body has been sealed in an airtight container and placed in a non-transparent, sturdy, sealed coffin; or
 - (b) in any other way in public unless the body has been placed at least in a container.
- (5) No coffin or container in which a body has been placed may be conveyed unless –
 - (a) the outer surface of such coffin or container is free from any liquid or any other unhygienic matter originating from such body; and
 - (b) offensive odours are absent.
- (6) The person responsible for the conveyance of a body shall, at the expense of the person on whose behalf the body is conveyed, ensure that if the body conveyed by him or her gives off an offensive odour, or if any liquid or other unhygienic matter originating from a body is present on the outer surface of a coffin or container, such coffin or container is taken forthwith to the nearest mortuary or undertaker's premises, where the necessary measures shall be taken to eliminate the offensive odour or to free the outer surface of such coffin or container from the said liquid or unhygienic matter.

Measures regarding the import and export of bodies

18. (1) (a) No person may import a body unless he or she has a written authorisation by the Director-General or a person specifically designated by him or her and which is valid for a period of 30 days after the date of issue.
- (b) If a body is imported without authorisation the Director-General or a person specifically designated by him or her may order that such body be kept in a mortuary or at an undertaker's premises at the expense of the person who imported the body until the necessary authorisation has been issued: Provided that if the prescribed authorisation is not issued within 30 days after the date of the order, the Director-General or a person specifically designated by him or her may order in writing that such body be buried or dealt with in the way referred to in the order at the expense of the person who imported the body.
- (2) Any person requiring a written authorisation referred to in subregulation (1) (a) shall apply to the Director-General or a person specifically designated by him or her and shall furnish the following particulars and documents:
- (a) A death certificate with at least the deceased's name, the date and place of death and the cause of death, in one of the official languages of the country;
- (b) the name and export permit of the country from which the body is to be imported;
- (c) the name of the border post where the body is to be imported, the type of transport to be used to import the body and convey it to the place of burial;

- (d) the name of the place in the Republic where burial of the body is to take place or if the body will not be buried the reason why the body is being brought in;
 - (e) an embalming certificate, where necessary unless where embalming is prohibited for religious reasons.
- (3) The provisions of this regulation shall also apply to the body of a person that has died in transition on a boat or aircraft the moment that the body is being brought into the Republic, irrespective of whether such body is to be buried in the Republic.
- (4) The authorisation referred to in subregulation (1) (a) shall be in the possession of the person responsible for the conveyance or burial of the body and shall be produced on demand to a health officer.

Measures regarding the disinterment of bodies

19. (1) No person may disinter a body or remove a body from any grave unless the following measures are taken:

- (2) The disinterment or removal of a body shall be carried out under the supervision of an environmental health practitioner of the local authority in whose area of jurisdiction the body is buried: Provided that if the local authority concerned does not have the services of an environmental health practitioner.
- (3) The local authority may use the services of an environmental health practitioner of another local authority or an environmental health practitioner in private practice to perform the duties as referred to in this regulation;
- (4) Only persons with direct involvement may be present at the disinterment or removal of a body and no dogs or other animals may be allowed at the grave;
- (5) Persons handling a body shall be supplied with and wear protective overwear, gloves and face masks which cover at least the nose and mouth;

(6) If demanded by an environmental health practitioner, the grave and the body shall be treated with a disinfectant or other protective measures demanded by an environmental health practitioner;

(7) Washing facilities shall be available at the grave for the cleansing of persons handling the body;

(8) A body shall be placed in a non-transparent and closely sealed airtight container immediately after it has been disinterred and be handled in such a way that no nuisance or health hazard is caused;

(9) During the disinterment or removal of a body the grave shall not be left unguarded and immediately after the remains have been removed such grave shall be covered or sealed.

CHAPTER 5

APPOINTMENT AND FUNCTIONS OF INSPECTORS OF ANATOMY AND INVESTIGATING OFFICERS

Inspectors of anatomy

20. (1) The provincial head of department of health in each province may appoint a person in the provincial department as an inspector of anatomy.
- (2) (a) An inspector of anatomy shall exercise the powers and perform the duties conferred or imposed upon or delegated or assigned to her or him by or under these regulations, subject to the control and directions of the provincial head of department of health or the directions of the Director-General.

- (b) The provincial head of department of health, or any other officer in the full-time employment of the provincial department designated by her or him, may exercise any power conferred upon an inspector of anatomy.
- (3) An inspector of anatomy shall exercise her or his powers and perform her or his duties in an area defined by the provincial head of department of health.
- (4) The appointment of an inspector of anatomy and the definition of the area within which she or he may exercise her or his powers and shall perform her or his duties shall be made known in the *Government Gazette*.

Investigating officers

- 21. (1) If the Director-General or provincial head of department of health appoints any person who is not in the full-time employment of the State as an investigating officer in any particular case to investigate any matter falling under these regulations or may so appoint such person to assist an inspector of anatomy or inspector of blood transfusion services with any matter which falls within the powers and duties of such relevant inspector.
- (2)
 - (a) An investigating officer, may, subject to the control and directions of the provincial head of department of health or the Director-General, for the purpose of the investigation for which she or he has been appointed, exercise any power conferred on an inspector of anatomy or an inspector of blood transfusion services under the Regulations Regarding Blood and Blood Products;
 - (b) The Director-General or the provincial head of department of health shall furnish an investigating officer with a letter of appointment, signed by the Director-General or the provincial head of department of health.

- (c) An investigating officer shall on request produce for inspection the letter of appointment furnished to her or to him in terms of paragraph (b).

Powers of inspectors of anatomy

22. (1) An inspector of anatomy may –

- (a) at any reasonable time for the proper performance of her or his functions and without prior notice enter any premises –
 - (i) in or upon which a human body or tissue is used or stored is reasonably suspected to be used for any purpose in terms of the Act or these regulations;
 - (ii) in or upon which the production from tissue of any therapeutic, diagnostic or prophylactic substance or the supply of such substance so produced is carried on or is reasonably suspected to be carried on;
 - (i) in or upon which the artificial fertilisation of any person is effected or is reasonably suspected to be effected;
 - (ii) in or upon which any prescribed activity or process is carried on or reasonably suspected to be carried on; or
 - (iii) which are connected with or are reasonably suspected to be connected with any act or process referred to in paragraph (i), (ii), (iii) and (iv), and ;

provided that if an inspector of blood transfusion services has been appointed in terms of the Regulations Regarding Blood and Blood Products, paragraphs (iv), (v) and (vi) are not applicable to an inspector of anatomy;

- (b) examine any such premises or any body, tissue, product or substance or other object found therein or thereon or any activity or process carried out on in or upon those premises, and may open any package or container in or upon those premises which contains or is suspected to contain such body, tissue, product, substance or other object, in order to ascertain whether the provisions of the Act and these regulations are being complied with;
- (c) at any time demand from any person in or upon any such premises that she or he forthwith or at a time and place determined by the inspector produce to her or to him any register, record or other document which is in the possession or custody or under the control of that person or any other person on her or his behalf;
- (d) examine such a register, record or other document and require from any person referred to in paragraph (c) an explanation of anything appearing therein, and make copies thereof or extracts therefrom, or seize such a register, record or other document, if in her or his opinion it may afford evidence of an offence in terms of the Act or these regulations;
- (e) with regard to any matter which she or he is investigating, question, either alone or in the presence of another person, as she or he may deem fit, any person whom she or he finds in or upon premises entered by her or him in terms of paragraph (a) or whom she or he on reasonable grounds suspects to be or to have been employed in or upon such premises or to have possession or custody of or control over anything referred to in this regulation;
- (f) order any person contemplated in paragraph (c) or (e) to appear before her or him at a time and place determined by her or him,

and at that time and place question that person with regard to any matter which she or he is investigating;

- (g) remove and bury the remains of a human body or tissue which is kept in or upon premises entered by her or him if she or he deems it advisable, and recover the cost in connection with the removal and burial from the institution or person under whose care the body or tissue concerned was immediately before such removal and burial.

- (2) Any person who is in charge of any activity or process referred to in subregulation (1) in respect of which any premises contemplated in subregulation (1) are occupied or used, and any person employed by such person, shall at all reasonable times render such assistance –

- (a) as an inspector of anatomy may require in the exercise of her or his powers under that regulation;
- (b) as the provincial head of department of health or any officer referred to in regulation 17(2)(b) may require; or
- (c) as an investigating officer may require in the exercise of his or her powers.

Reports

- 23. An inspector of anatomy shall furnish the provincial head of department of health as well as to the Director-General –

- (a) as soon as possible after the thirty-first day of December of each year a report in respect of her or his work during the year which ended on that day and in respect of the operation of the provisions of the Act and these regulations in so far as they apply to her or to him;
- (b) any other report required by the member of the executive council or the Minister from time to time in respect of the activities of the inspector.

CHAPTER 6

GENERAL AND SUPPLEMENTARY PROVISIONS

Prohibition of publication of certain facts

24. (1) No person shall publish or make known any fact whereby the identity of –

- (a) a deceased person whose body or any specific tissue thereof has been donated;
- (b) the donor of the body of a deceased person or any specific tissue thereof;
- (c) a living person from whose body any tissue, blood or gamete has been removed or withdrawn for any purpose; or
- (d) the person who has given her or his consent to the removal of any tissue, blood or gametes from a living person for such purpose;

may possibly be established, unless consent thereto was granted.

(2) No person shall publish to another person any fact whereby the identity of the recipient of any tissue removed from another person before or after the death of the said person may possibly established, unless –

- (a) in the case of a recipient who is still alive at the time of such publication, that recipient before such publication granted her or his consent thereto in writing; or
- (b) in the case of a recipient who at the time of such publication has died –
 - (i) that recipient before her or his death granted consent to such publication in writing; or

- (ii) that recipient did not before her or his death indicate in any manner that she or he would not be prepared to grant such consent and the spouse, partner, major child, parent, guardian, major brother or major sister of the recipient before such publication granted consent in writing.

Offences and penalties

25 Any person who –

- (a) except in so far as it may be permitted by or under any other law, acquires, uses or supplies a body of a deceased person or any tissue, blood or gamete of a living or deceased person in any other manner or for any other purpose than that permitted in the Act and these regulations;
- (b) refuses or fails to comply to the best of her or his ability with any demand, requirement or order of an inspector of anatomy or an inspector of blood transfusion services or any other person made or given in terms of any provision of the Act and these regulations; or
- (c) hinders any person in the performance of her or his duties in terms of the Act and these regulations;

shall be guilty of an offence and liable on conviction to a fine or imprisonment for a period of 10 years or to both fine and imprisonment.

Exclusive rights in respect of bodies of deceased persons, tissue, blood and gametes

26. Any person who acquires the body of a deceased person or any tissue, blood or gamete by virtue of any provision of the Act and these regulations, shall, subject to any restrictions in terms of the Act or any other law and provided she or he uses the body, tissue, blood or gamete for the purposes for which it has been

donated, handed over or supplied to her or to him, on receipt of that body, tissue, blood or gamete acquire exclusive rights in respect thereof.

Repeal

27. The regulations published under Government Notice No. R 2876 of 29 December 1989 are hereby repealed.

**DR A MOTSOLEDI
MINISTER OF HEALTH**