The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act

The Act was published in "Official gazette of Montenegro", no. 76/2009 from 18.11.2009.

I. GENERAL PROVISIONS

Article 1

This Act shall regulate manner and procedure for removal of human body parts (organs and tissues) from living or dead person (hereinafter: "the donor") for transplantation into another person's body for the purposes of medical treatment, conditions under which the procedures of removal and transplantation of body parts shall be carried out in health care institutions, conditions which health care institutions have to fulfill in order to perform these procedures, as well as other questions relevant for the procedure of removal and transplantation of body parts for the purposes of medical treatment.

Provisions of this Act referring to tissues shall be applied also to cells, including also the haematopoietic stem cells.

The provisions of this Act shall not cover organs and tissues for reproduction, parts and tissues of embryo or fetus, the blood, blood components and blood derivatives.

Article 2

The removal and transplantation of body parts for the purposes of medical treatment shall be carried out in accordance with the appropriate professional standards of medical science and practice and with respect to the ethic principles.

The removal and transplantation of body parts for the purposes of medical treatment shall be performed only when it is medically justified, when that is the only possible way of treatment and under the conditions laid by this Act.

Article 3

The removal and transplantation of human body parts shall be performed with application of principles:

- of consent, i.e. consent of recipient and donor;
- of donation for the sake of treatment;
- of uncommercial donation;
- of anonymity of donors and recipients.

Article 4

The removal and transplantation of body parts shall be carried out when all necessary medical investigations and other medical treatments have been carried out, based on which it is determined that the procedure represents welfare for recipient, and according to medical criteria an acceptable health risk for the donor and that the success of the intervention can be predicted with probability.

Article 5

In procedures of removal and transplantation of body parts protection of donor's and recipient's identity, personal dignity and other personal rights and freedoms shall be guaranteed.

Article 6

No payment shall be given or accepted as compensation for removed body parts.

The compensation, in terms of paragraph 1 of this Article shall not be deemed compensation of salary, travel costs, costs of stay in health care institution, medical examinations, laboratory investigation, medical treatments during and after removal of body parts, as well as the compensation for damages caused by incompetent and negligent treatment contrary to prevailing medical criteria.

Article 7

It is prohibited to traffic body organs, to announce the need for them and offer of body parts in media or by means of any other and media for advertisements or mediation in these matters.

Article 8

Procedure of removal and transplantation of body parts may be carried out only in health care institutions which meet conditions stipulated by this Act.

Medical workers who participate in the procedure of removal and transplantation of body parts are obliged to take all standard measures and activities in order to prevent risk from transferring of contagious or any other disease to recipient and to avoid influences to preservation of body parts for transplantation, in accordance with the regulation of the ministry competent for health affairs (hereinafter: “the Ministry”).

Article 9

Data on donor and recipient of body parts shall be a professional secret.

The disclosure of any data whatsoever on the dead donor to the recipient or passing of any information on the recipient to the relatives of the dead donor, shall not be permitted.

The recipient’s physician shall have the right to access to medical data of the donor, when the medically justified reasons require so.

Data referred to in the paragraph 1 of this Article shall be collected, stored and disclosed in accordance with a separate law.

Article 10

Funds for the procedures of removal and transplantation of body parts for the purposes of medical treatment, i.e. for health protection related to these procedures, as well as for the monitoring of the health condition of the donor and recipient shall be provided as rights from the obligatory health insurance.

Article 11

Ministry, health care institutions and medical workers involved in the procedures of removal, transplantation, preserving and exchange of body parts and other health care institutions shall work together on successful implementation, promotion and popularization of the procedure of donating of body parts.

Popularization of donation of body parts shall mean informing public about medical, legal, social, ethic and other aspects significant for implementation of the procedure of donation of body parts for the purpose of medical treatment.

II. WAITING LIST

Article 12

Health care institutions in which the removal, i.e. transplantation of the body parts is performed shall deliver to the Ministry the list of persons for which it was determined that the transplantation of body parts is the only way of treatment, based on which a waiting list shall be prepared.

Waiting list shall be made according to types of needed body parts. Removed body parts are awarded to recipients based on the waiting list in accordance with the transparent, just and common medical criteria.

Manner and procedure of making and managing the waiting list and submitting of data from health care institutions, waiting criteria, conditions for selection of the best recipient and awarding of removed body parts for the purposes of medical treatment and other matters important for managing of waiting list shall be prescribed by the Ministry.

III. PROCEDURE OF REMOVAL AND TRANSPLANTATION OF BODY PARTS

1. Removal of body parts from a living donor

Article 13

Body parts from may be removed from a living donor only for the purpose of the medical treatment, provided there is no appropriate body part of a dead donor available or any other form of medical intervention.

Article 14

Health care institutions which fulfill the conditions for removal of body parts shall form Ethic Committee.

Ethic Committee from the paragraph 1 of this Article shall decide on each case of removal of human body parts from a living donor for transplantation to the recipient.

Article 15

Body parts shall be removed only from persons over 18 years of age under condition that that person is capable of work and of making judgment.

Before the removal of body parts, adequate medical examinations and interventions for estimation and reduction of physical and psychic risks for health of the donor shall be conducted.

Removal of body parts may be performed only if according to medical criteria the risk for life and health of the donor is within limits of acceptable and corresponds to expected benefit for the recipient.

Donor is entitled to be informed about the results achieved in the procedures, in terms of paragraphs 2 and 3 of this Article, which are relevant to his health.

Article 16

Removal of body parts from a living donor is allowed provided that the donor has given for that intervention his written consent authorized by competent authority.

Written consent is freely expressed will of the donor, which can be recalled until the beginning of the intervention.

Consent of the donor of body parts refers only to the planned medical intervention, i.e. only to removal of certain body parts, and it may also be given with condition to perform the transplantation to a certain person.

Procedure for giving consent, contents of the consent, as well as the statement on revocation and amendments shall be determined by the Ministry.

Article 17

Doctor involved in the removal of body parts is obliged to inform the donor about the nature, purpose and course of the procedure, chances for success and usual risks of removal of body parts.

Donor shall also be informed about the right to an independent consultation about the risks to health from a doctor who is not involved in the removal or transplantation of body parts, i.e. who is not a personal physician of the recipient, and about other rights stipulated by this Act.

Record shall be drafted on actions from paragraph 2 of this Article, which shall be kept in the medical records, together with the donor’s consent.

Article 18

Notwithstanding the Article 15 paragraph 1 of this Act, Ethic Committee of the health care institution may approve removal of regenerative tissue from an underage person and form a person with over 18 years of age who is not capable of making judgment, provided that the following conditions were met cumulatively:

- there is no available compatible donor capable to give consent;
- recipient is a brother or a sister of a donor;
- donation is performed for saving the life of recipient;
- regular consent of legal representative or guardian of the donor has been acquired, and if he does not have them, opinion of the competent center for social work;
- potential donor and recipient do not object.

Provisions of the paragraph 1 indent 2 and 3 of this Article shall not apply to cells, provided it is determined that their removal includes only minimum risk and minimum strain to the donor.

Article 19

Notwithstanding the Article 15 paragraph 1 of this Act, collecting and storage of the haematopoietic stem cells from the umbilical cord separate from a living newborn shall be permitted. Cells collected in such a manner shall be used for transplantation into any person, whether related to the donor or not.

The procedures of collection, storage and usage of haematopoietic stem cells are determined by the Ministry.

Article 20

Monitoring of the health condition shall be provided to the donor of body parts after the performed intervention of removal of body parts.

2. Removal of body parts from a dead donor

Article 21

Removal of body parts from a dead person is performed with respect to his dignity and feelings of family members and by taking all the measures in order to return outer looks of a dead donor.

Article 22

Body parts may be removed from a dead person only if that person as a person of age, capable of work and of making judgment has given written voluntarily consent for this procedure with his personal physician.

Before the removal of body parts, doctor shall determine the existence of statement, i.e. to check if the statement has been revoked and shall draft a record about that, which shall be kept in medical records.

Procedure for giving consent, contents of the consent, manner of identification of the giver of consent and statement on revoking shall be stipulated by the Ministry.

Article 23

Notwithstanding the Article 22 paragraph 1 of this Act, the removal of body parts from an underage dead person for transplantation into other person for the purpose of medical treatment may be performed only with written consent of both parents.

Consent may also be given by one parent if other parent is dead or pronounced dead.

Doctor shall file the consent of parents on removing body parts from an underage dead person in the medical records.

Procedure of giving consent and contents of the consent referred to in the paragraph 1 and 2 of this Article shall be stipulated by the Ministry.

Article 24

Body parts of a dead person who is foreign citizen or is a person with no residence in Montenegro, may be taken for transplantation under the same conditions as for the citizens of Montenegro, unless provided otherwise by international agreement.

Article 25

Body parts from a dead person may be taken for transplantation into other person, after the death of the donor has been established and confirmed in compliance with medical criteria and set procedures.

Death of the person from which the body parts are removed for transplantation has occurred if, based on medical criteria, cessation of brain work has been established and confirmed.

Commission of the health care institution constituted of at least three doctors shall determine death of person whose body parts may be taken for transplantation.

Members of commission may not participate in removal or transplantation of the body part from the dead person whose death they have determined, i.e. confirmed, and they shall not monitor the health condition of the potential recipient, after this intervention.

Manner, procedure and medical criteria for death determination of person whose body parts may be removed for transplantation for the purpose of medical treatment, as well as the detailed composition of the Commission shall be stipulated by the Ministry.

3. Transplantation

Article 26

Transplantation of body parts shall be performed in case when that is the only possible way of medical treatment of persons who suffered the total damage of part or parts of body, or persons who, due to the damage of body part or body parts, i.e. body parts suitable for transplantation, have the reduced quality of life and who cannot be treated with other methods of comparative efficiency and provided that all treatment procedures were conducted in accordance with medical standards and practice.

Transplantation of body parts for the purpose of medical treatment, in terms of paragraph 1 of this Article, shall be carried out upon approval of Medical Board of the health care institution.

Article 27

Transplantation of body parts may be performed only with written consent of informed recipient of age, capable of work and making judgment.

For underage persons and persons over 18 years of age who are not capable of work or of making judgment, consent shall be given by a legal representative, i.e. guardian.

For persons who are not able to declare themselves, consent may be given by a spouse, parent or direct or collateral blood relative to second degree.

Consent for transplantation shall be given as free expressed will and in prescribed manner, and shall be kept in medical records.

Form, contents and manner of giving consent shall be determined by the Ministry.

Article 28

The doctor involved in the procedure of transplantation of body parts shall inform the recipient about the nature, purpose and course of the transplantation, probability of its success and usual risks, and shall draft the record about it in the medical records.

In cases of urgency and endangerment of recipient's life and when there is a compatible part of a human body, doctor may perform the procedure of transplantation also without the consent, and shall draft the record about it in the medical records.

Article 29

Monitoring of health condition even after the performed procedure of transplantation shall be provided to the person into whom the transplantation of body parts was performed, in accordance with this Act.

3. Handling of removed body parts

Article 30

When during some intervention a body part is taken, it can be stored and used for different purpose from the one for which it was taken, only after obtained consents in accordance with the procedure stipulated by this Act.

IV. HEALTH CARE INSTITUTIONS FOR REMOVAL AND TRANSPLANTATION OF BODY PARTS

Article 31

Removal, transplantation, determining of compatibility, storage and exchange of body parts shall be performed by health care institutions or parts of health care institutions that possess the decision of the Ministry to perform these procedures.

Conditions in terms of premises, equipment and necessary professional staff which institutions from paragraph 1 of this Article are obliged to meet, as well as the manner of performing quality control checks of work of these institutions shall be stipulated by the Ministry.

Article 32

Provisions of the Law on Health Protection shall be applied to establishment, work, quality control checks of work and other matters significant for work of health care institutions from Article 31 of this Act, unless otherwise provided by this Act.

Article 33

Removal of body parts from a living donor for transplantation may be carried out only by health care institution which shall also perform the transplantation of body parts.

Article 34

Health care institutions from the Article 31 of this Act shall cooperate having as the objective exchange of body parts.

If the transplantation is not carried out in a health care institution in which the removal of body parts was performed, manner of storage and transport of body parts meant for transplantation shall be done in accordance with a special regulation of the Ministry.

Health care institutions from the Article 31 of this Act shall cooperate also with authorised institutions of other countries having as the objective exchange of body parts, in a manner determined by the Ministry.

Article 35

Analyses of body parts, before using, shall only be performed in laboratory which meets the conditions regarding application of optimal level of accepted medical standards, premises, staff, technical or other conditions, stipulated by the Ministry.

Decision on fulfillment of criteria from the paragraph 1 of this Article shall be rendered by the Ministry.

Article 36

In health care institutions from Article 31 of this Act, the Minister competent for health matters, upon proposal of the director of that health care institution, appoints the person responsible for implementation of procedures of removal and transplantation of body parts (hereinafter: “the Coordinator”).

Coordinator organises and coordinates the work in a health care institution from paragraph 1 of this Article, organises the cooperation with other health care institutions from Article 31 of this Act and performs other tasks in accordance with the regulation of the Ministry.

V. REGISTRY AND RECORDS

Article 37

Ministry shall keep the registry of persons who gave their consent for removal of body parts in case of their death for transplantation into the body of other person for the purpose of medical treatment in accordance with this Act.

Manner and procedure of keeping and enlisting into the registry from the paragraph 1 of this Article, kept data, keeping and protection of data and the procedure for access to data, as well as the way of giving consent for removal of body parts shall be stipulated by the Ministry.

Article 38

Health care institutions from the Article 31 of this Act shall keep records on personal data on donors and recipients, on each removal and transplantation of body parts, exchange of body parts, successfulness of interventions, eventual complications, health condition of donor

and recipient after the performed intervention, measures taken to provide quality of performing of interventions and other data in accordance with a special Law.

Coordinator submits to the Ministry reports on data from the paragraph 1 of this Article by the end of the first quarter of the current year for previous calendar year, and even earlier upon the request of the Ministry.

VI. SUPERVISION

Article 39

Supervision over the implementation of this Act shall be performed by the Ministry, in accordance with the Law.

VII. PENAL PROVISIONS

Article 40

A fine amounting from two hundred- to three hundred-time minimum wage in Montenegro shall be imposed on a legal entity, if:

1) it does not submit to the Ministry the list of persons for who the only possible way of treatment is transplantation of body parts (Article 12 paragraph 1);

2) it does not form Ethic Committee which shall decide on each case of removal of body parts from a living donor for the purpose of transplantation to recipient (Article 14);

3) it does not inform the donor about the nature, purpose and course of intervention, probability for its success and usual risks of removal of body parts (Article 17 paragraph 1);

4) it fails to inform the donor about the right to independent consultation about the health risks and from a doctor who shall not participate in removal or transplantation of body parts, i.e. who is not a personal physician of the recipient (Article 17 paragraph 2);

5) it fails to draft record on informing a donor about the right to independent consultation about the health risks and from the doctor who shall not participate in the removal or transplantation of body parts, i.e. who is not a personal physician of the recipient, as well as about other rights stipulated by this Act, and if it does not keep it in the medical records (Article 17 paragraph 3);

6) it fails to provide to the donor of body parts monitoring of health condition after the performed intervention of removal of body parts (Article 20);

7) it violates the dignity of dead person or members of his family on the occasion of removal of body parts from dead donor (Article 21);

8) it takes the body part from a dead donor, and does not determine the existence of statement, or does not check if the statement has been revoked (Article 22, paragraph 2);

9) it fails to draft record on existence of the statement of the dead donor, or its revocation (Article 22 paragraph 2);

10) it fails to file the written consent of parents into the medical records (Article 23 paragraph 3);

11) the members of the Commission who determined, i.e. confirmed the death of dead person or monitored health condition of potential recipient after this intervention take part in removal or transplantation of body parts from that person (Article 25 paragraph 4);

12) it fails to inform the recipient of body parts about the nature, purpose and course of transplantation, probability for its success and usual risks (Article 28 paragraph 1);

13) it fails to draft the record in medical records on informing the recipient of body parts about the nature, purpose and course of transplantation, probability for its success and usual risks (Article 28 paragraph 1);

14) performs in urgent procedure transplantation of body part, and fails to draft record in the medical records about that (Article 28 paragraph 2);

15) it fails to provide to person to whom the transplantation was performed monitoring of health condition after the performed intervention of transplantation (Article 29);

16) it fails to do the transplantation of the removed body part from the living donor in the same institution (Article 33);

17) fails to keep and store records on procedures stipulated by the Article 38 paragraph 1 of this Act;

18) fails to submit to the Ministry the report by the end of the first quarter of the current year for previous year (Article 38 paragraph 2).

A fine amounting from ten- to twenty-time minimum wage in Montenegro shall be imposed on a responsible person in the legal person for an offence referred to in the paragraph 1 of this Article.

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 41

Procedures of removal and donation of body parts which were initiated before the beginning of application of this Act shall be finished according to regulations which were effective until the beginning of implementation of this Act.

Article 42

Regulations for implementation of this Act shall be enacted within nine months from the day this Act enters into force.

Until enactment of regulations from paragraph 1 of this Article, regulations issued pursuant to previous laws shall be applied, provided they are not contrary to this Act.

Article 43

On the day this Act enters into force Law on Removal of Human Body Parts, Organs and Tissue for Transplantation for the Purpose of Medical Treatment (“Official gazette of FRM” no. 17/83) and Law on Conditions for Removal and Transplantation of Human Body Parts (“Official gazette of FRY” no.63/90) shall cease to be valid.

Article 44

This Act shall enter into the force on the eighth day following its publication in the “Official gazette of Montenegro”, and shall be applied after expiry of one year from its entering into force.