Act No. 285/2002 Sb.

Act on Donation, Collection and Transplantation of Tissues and Organs and Amendments to Certain Acts (Transplantation Act)

Effective from **01.09.2002**

285
LAW of 30 May 2002
Law on Donation, Collection and Transplantation of Tissues and Organs and Amendments to Certain Acts (Transplantation Act)
The Parliament passed the following Act.

PART ONE

DONATION, COLLECTION AND TRANSPLANTATION OF TISSUES AND ORGANS

ARTICLE I

GENERAL CONDITIONS

§ 1

Subject of presentation

(1) This Act incorporates the relevant regulations of the European Union [21]) and lays down norms for ensuring the quality and safety of human organs (hereinafter referred to as "organ") intended for transplantation into the human body in order to ensure a high level of protection of human health during their examination, characterization, procurement, preservation, transport and transplantation.

(2) This Act further regulates the conditions of donation, procurement and transplantation of tissues, cells and organs carried out exclusively with the purpose of providing health services [1]). As far as the quality and safety of tissues and cells is concerned, the law governing human tissues and cells is applied [7a]).

§ 2

Basic concepts

For the purposes of this Act, the following definitions shall be applied.

(a) Organ is an autonomous and viable part of the human body consisting of a structured arrangement of different tissues, which maintains its structure, vascular supply and ability to perform physiological functions with a significant degree of autonomy; a part of an organ is also considered to be an organ if it serves the same purpose in the human body as the whole organ, while maintaining his structure and vascular supply.

(b) Tissues and cells are the structural components of the human body. Among these surgical remains, hematopoietic stem cells derived from bone marrow, peripheral and umbilical cord blood are included; organs, blood and its components, germ cells, embryonic and fetal tissues and organs, hair, nails, placenta and waste products of body metabolism (hereinafter referred to as "tissue") are excluded.

c) A potential donor is a patient who, according to his or her state of health, is presumed to be deceased and suitable for tissue or organ collection, or the body of a deceased person in whom death has been proven and who is presumed to be able to take tissue or organ.

d) The donor is the person who donates an organ or tissue, whether the donation occurs during his or her lifetime or after his or her death.

e) The donation can take place following an irreversible loss of function of the entire brain, including the brainstem, or irreversible circulatory arrest as well.

f) A person registered in the National Register of Persons Waiting for Organ Transplant is a person who is waiting for organ transplant.

g) The recipient is the person receiving the transplanted organ or tissue,

h) The procurement is all procedures necessary for the acquisition of tissues or organs for transplantation, including examinations to assess the donor's medical suitability and his preparation for procurement.

i) Organs or tissues can be donated and transplanted.
j) Transplantation is the process aimed at restoring specific functions of the human body by transferring an organ or tissue from a donor to the recipient's body.
k) Donor characterization is the collection of relevant information on the donor's characteristics that is needed to assess his medical suitability for organ or tissue donation, in order to make an appropriate assessment and minimize the risk to the recipient and to optimize organ allocation.
l) Organ characterization is the collection of relevant information on its characteristics needed to assess its suitability for transplantation, in order to assess and minimize the risk to the recipient and to optimize the allocation of the organ.
m) Preservation occurs by the use of chemicals, changes in environmental conditions or other means in order to prevent biological or physical damage to an organ or to slow down such damage for the period from collection to transplantation.
n) A serious adverse reaction is an untoward and unexpected event related to the donation, investigation, characterisation, procurement, preservation or transfer of an organ intended for transplantation which could lead to the transmission of a communicable disease, to death, or to the endangerment of the life, health or faculties of the patient causing or prolonging patient's hospitalisation or illness.
o) A serious adverse reaction is an unexpected response by a living donor or recipient, including a communicable disease, which could be related to the donation, investigation, characterization, procurement, preservation or transfer of an organ intended for transplantation causing death, life-threatening injuries, impairment of health or disability or results in or prolonging his or her hospitalization or illness.
p) Working procedures are written instructions describing the various stages of the process from organ donation to transplantation, including the materials and methods to be used and the expected overall outcome.
q) Traceability options:

1. locate and identify the organ during each stage of its treatment, as well as its disposal site;
2. identify the living or deceased donor;
3. identify the healthcare provider involved in the organ procurement;
4. identify the recipient at the transplant centre;
5. locate and identify all necessary data concerning products and materials which come into contact with the organ.

r) A close relative is a spouse, a registered partner, a sibling or first-degree relative.

ARTICLE II

TISSUE AND ORGAN COLLECTION
Part 1

Collection of tissues and organs from living donors

§ 3

Permissibility of tissue and organ collection from a living donor
(1) The procurement of tissues or organs (hereinafter referred to as "procurement") from a living donor, unless otherwise specified below, may be carried out only if

a) carried out exclusively in the interest of the therapeutic benefit for the recipient,
b) no suitable tissue or organ from a deceased donor is available at the time of procurement and there is no other treatment method of comparable effect,
c) the donor, as a person qualified to give free, informed and specific consent in the manner prescribed by this Act (§ 7), has expressed his consent,
d) it is about

1. a part of an organ capable of regeneration or adaptation (hereinafter referred to as "renewable tissues"),
2. one of the functional paired organs,
3. uterus when it comes to treating infertility caused by a dysfunctional or missing uterus.

(2) The removal of organs from a living donor, unless otherwise provided, may be carried out for the benefit of a recipient

a) who is a person close to the donor, if the donor has given free, informed and specific consent (§ 7) in relation to this person,

b) who is not a person close to the donor, only on condition that

1. the donor has explicitly expressed in a demonstrable manner his or her will to donate his or her organ to that recipient; the expression of will (hereinafter referred to as "the statement") shall be put in writing and shall bear the official signature of the donor; the statement is an integral part of the donor's medical records,

2. the Ethics Committee consent to this donation according to § 5 par.5 let. a).

(3) Procurement from a living donor shall not be performed if

a) it is reasonably foreseeable that the donation could seriously endanger the health or life of the donor,

b) the donor is a person serving a custodial sentence, in custody or in protective treatment, with the exception of donations between children and parents, siblings and spouses, or

c) there is a reasonable suspicion, based on an assessment of the donor's medical suitability, that the donor is suffering from a disease or condition that could endanger the health or life of the recipient. This is not applied if the risk of harm to the recipient's health is negligible compared to a life-saving transplant. Conditions for the prevention of human immunodeficiency virus infection shall be laid down in special legislation. **[4])**

§ 4

Protection of persons who have not acquired full autonomy, persons with limited autonomy and persons who, due to their current state of health, are not able to consider all the consequences of carrying out the collection of renewable tissue for their own health

(1) From donors who are persons who have not acquired full autonomy, persons with limited autonomy (hereinafter referred to as "person who is not fully independent") or persons who have consented to the procurement, but with regard to their current state of health may be reasonably assume that, despite full instruction, they could not consider all the consequences associated with the collection of renewable tissue (hereinafter "person unable to consent"), the collection of renewable tissue may be performed, unless otherwise specified below, only if

a) there is no suitable donor available who is able to give explicit and specific consent,

b) the recipient is the sibling of the donor,

c) the donation represents an opportunity to save the recipient's life,

d) the legal representative of the donor, who is not fully independent, has consented to this collection in accordance with § 7, Par. 4,

e) the Ethics Committee has stated pursuant to § 5 par. 5 let. (b) to consent to such collection, and

f) the donor does not object to the donation.

(2) The provisions of par.1 letter b) and c) shall not apply to the procurement of cells if such procurement presents only a minimal risk to the health and life of the donor.

§ 5

The Ethics Committee

(1) The Ethics Commission is an independent commission established and abolished by the statutory body of the health service provider performing the collection of the organ by the donor for the benefit of the recipient [§ 3 par. b)], or renewable tissues to persons who are not fully independent or to persons unable to give consent (§ 4). The Ethics Committee may be established as a standing committee or, as required, for individual cases.

(2) The Ethics Committee shall have at least 5 members; it shall consist of a doctor, a clinical psychologist and a lawyer. At least two thirds of the members of the Ethics Committee shall not be in an employment or similar relationship with the health service provider referred to in par.1. The chairman and other members of the Ethics Committee shall be appointed and dismissed by the statutory body of the health service provider. In performing the activities of the Ethics Committee, the chairman and members of the Ethics Committee shall not be bound by the instructions of the statutory body of the health care provider or the instructions of other senior employees of the healthcare provider. Members of the Ethics Committee shall be persons without personal interest or participation in the procurement of

a) an organ for the benefit of a recipient who is not a person close to the donor,

b) renewable tissue to a person who is not fully competent or unable of giving consent.

(3) The members of the Ethics Committee are obliged to maintain confidentiality of all facts they have learned in connection with the performance of their duties, except for cases where they can be disclosed with the consent of the donor, recipient or legal representative of a person who is not fully independent. The facts shall be disclosed with the consent of the persons referred to in the first sentence in such a way that it is not possible to obtain information about other persons and that anonymity between the donor and the recipient is respected (§ 20). A special legal regulation shall apply to the release of privacy statement of the members of the Commission, [1] which lays down the rights and obligations of health professionals in the provision of health services. The activity of the members of the Ethics Committee shall be an act in the general interest, during which the employee is granted time off work with wage compensation in the amount of average earnings to the extent necessary. [7]

(4) Meetings of the Ethics Committee shall be chaired by the chairman. The Ethics Committee decides by a majority of votes of its members. In case of a tie, the chairman vote shall prevail.

(5) On the basis of a written request submitted by the statutory body of the health service provider that established the commission, the Ethics Commission shall grant written consent or disagreement with the procurement of

a) an organ for the benefit of a recipient who is not related to the donor,

b) renewable tissues to a person who is not fully competent or unable to give consent.

Consent or disagreement is part of the medical records of a person who intends to donate an organ or tissue, a person who lacks full independence or a person unable to give consent. The Ethics Committee shall send a copy of the document to the Transplant Coordination Centre within 7 days of granting the consent or expressing disagreement.

(6) The application for consent must include

a) information on the health status of the donor, of the person who lacks fully independence or of the person unable to give consent, which are decisive for the assessment of the possible collection of renewable tissue,

b) a statement by a clinical psychologist, requested by the doctor assessing the person's medical fitness, on the capacity of a person who is not fully independent or unable to express consent to the procurement,

c) information on the state of health of the recipient of an organ or renewable tissue,

d) a copy of the full instruction and informed consent of the organ donor or the donor's legal representative (§ 7, Par.1 and 2), or the statement of a person who is not fully independent (§ 7, Par.6),

e) a copy of the full instruction and consent of the person unable to give consent,

f) a copy of the donor's statement pursuant to § 3 par.2 let. b),

g) the time limit within which the Ethics Committee is required to give its consent or disagreement with the donation of an organ or renewable tissue to a person who is not fully independent or unable to give consent.

(7) If necessary, the Ethics Committee may invite the organ donor or legal representative of a person who is not fully independent to the meeting on granting consent or disagreement with the procurement. The Ethics Committee shall always invite:

a) a person who is not fully independent, if the clinical psychologist has stated in his or her statement that this person is able to comment on the procedure,

b) a person unable to give consent,

c) the organ donor referred to in § 3 par.2 let. b); in this case, in addition to medical considerations, the Ethics Committee shall also ascertain and assess the reasons that led the donor to donate the organ.

(8) In the case of consent given pursuant to par.5, the Ethics Commission shall supervise the course of the procurement and the preservation of the rights of the donor, the person who is not fully independent or the person unable to give consent.

(9) The Ethics Committee shall keep proper registers of its activities, in particular written working procedures, a list of members indicating their professional competence, submitted applications and documents, minutes of meetings, reports concerning its activities and assessment of applications for at least 10 years. In the event of dissolution of the Ethics Committee, the statutory body of the health service provider in which the Ethics Committee was established shall ensure that the documentation is properly preserved.

§ 5a

If the removal of the uterus is in favour of a recipient related to a living donor, § 5 shall apply mutatis mutandis.

§ 6

Assessment of the medical fitness of a living donor

(1) The medical fitness to donate tissue or organs of a living donor shall be assessed before they are donated. To this end, medical examinations and procedures shall be carried out to assess the living donor's health and the potential risks to the donor's health and life associated with tissue or organ donation. At the same time, procedures must be established to reduce as much as possible the risks to the health and life of the donor posed by the removal of the tissue or organ without compromising the quality and viability of the removed tissues or organs. Donor characterisation and organ characterisation shall be an integral part of the assessment of donor fitness.

(2) The health service provider performing the donation is responsible for assessing the donor's medical fitness to donate. In the case of tissue donation, the assessment of the donor's medical fitness shall be carried out is in accordance with the Act on Human Tissues and Cells [7a] **)** .

(3) The assessing doctor shall write down the assessment of the donor's medical fitness in a report, specifying the scope of the assessment and concluding on the donor's eligibility or ineligibility for donation. This record, signed and dated by the assessing doctor, is an integral part of the donor's medical records. Within 7 days of the donor's medical fitness assessment, the assessing doctor shall submit an extract from the medical documentation mentioned previously to the Transplant Coordination Centre.

(4) The healthcare provider who carried out the donation shall ensure the provision of preventive health care to the donor.

(5) Detailed conditions for assessing medical fitness, the scope of examination of a living organ donor and the scope of data required for the characterisation of this donor and for the characterization of organs from this donor shall be determined by a decree of the Ministry of Health (hereinafter "the Ministry").

(6) The donor or the legal representative of a person who is not fully independent may ask another doctor who is not involved in the procurement or other procedures related to transplantation to assess the health risks of the donation for the donor. The provisions of par.1 to 5 shall not apply to this assessment.

§ 7

Full instruction and consent

(1) The doctor assessing the medical fitness of a living donor is obliged to provide the donor with complete information about the purpose, nature and consequences of tissue or organ donation and the possible risks associated with it, including long-term risks. If the donor is a person who is not fully independent, his legal representative shall be given this information. The information must be comprehensible. The donor and the legal representative of the person who is not fully independent shall have the right to ask questions and the doctor is obliged to answer them. The information shall also include details on the rights and protection of the donor provided by this Act.

(2) The donor and the legal representative of a person who is not fully independent may request that another witness be present at the briefing. They shall be informed in advance of this possibility by the doctor providing complete information. The doctor shall write a report of the complete instruction with a brief summary of the content of the briefing, indicating the date when the instruction was given, which shall be signed by all persons involved. This report of the complete briefing of the donor or the legal representative of a person who is not fully independent is an integral part of the donor's medical records.

(3) The medical practitioner carrying out the collection shall repeat the complete instructions under the conditions set out in par.1 immediately before the collection.

(4) The consent of the donor or legal representative of a person who is not fully independent, expressed on the basis of a complete instruction pursuant to par.1, shall be free, informed and specific. It shall be put in writing, signed, dated and filed in the donor's medical records. Consent given in relation to the collection of tissue shall include a statement of the purpose for which it is to be used.

(5) The donor or legal representative of a person who is not fully independent may revoke his consent at any time. The doctor carrying out the donation is obliged to respect this revocation, unless irreversible acts have been carried out during the collection, the interruption of which would endanger the health or life of the donor.

(6) If persons who are not fully self-sufficient are able to sufficiently understand the consequences of carrying out or not carrying out the donation for themselves or for the recipient, it is necessary to provide them with full information. If the person mentioned in the first sentence expresses disagreement with the donation, this disagreement shall be respected.

(7) In the case of consent expressed in relation to the donation of tissues, the health care provider shall provide a copy of this consent, or an amendment thereto, to the tissue establishment [7a]) to which the tissue has been handed over. The transferring copy of the consent shall be confirmed by the transferring health care provider as being in conformity with the original.

§ 8

Condition of collection from a living donor

(1) The removal of an organ from a living donor shall be carried out only for the benefit of the person designated by the donor (§ 3 par.2). If a living tissue donor designes the donation to a specific person, such donation shall be carried out only for the benefit of that person.

(2) In the event that the donating tissue or organ cannot be transplanted in the designated person, it is necessary to request the donor’s consent, prior to the collection, to use the tissue or organ for another person. The reasons which led the competent doctors to decide that the tissue or organ cannot be transplanted shall be recorded in the donor's medical records.

§ 9

Transplantation of tissues or organs taken for reasons other than transplantation

(1) If a tissue or organ has been removed from a patient for a reason other than transplantation, it may be implanted by the recipient only if the patient has been informed of the consequences and possible risks of such removal and has consented to its use for transplantation before or after the removal of the tissue or organ.

(2) The provisions of § 7 shall apply mutatis mutandis when carrying out the instructions and obtaining consent pursuant to par.1.

Part 2

Collection from deceased donors

§ 10

Admissibility of collection from a deceased donor and requirements for the detection of death

(1) Donation from a deceased donor may be carried out only if death has been established. If the procurement from the deceased donor is to take place within 2 hours after the death, this collection shall not take place until the protocol referred to in par.2 has been signed.

(2) The detection of the death of a potential donor shall always be carried out by at least 2 doctors with the appropriate specialized competence, who have examined the donor independently of each other. The determination of the death of a potential donor shall be written down in a minutes, which acts as an integral part of the donor's medical records, in the case of an expected collection before 2 hours have elapsed from this finding. The death minutes shall be signed by the doctors who discovered the death.

(3) Death [§ 2 letter e)] is established by proving

a) irreversible circulatory arrest;

b) irreversible loss of function of the whole brain, including the brainstem, in cases where respiratory or circulatory functions are maintained artificially (hereinafter referred to as "brain death").

(4) In the event of the discovery of death by proving an irreversible circulatory arrest, the donation shall be carried out within 2 hours from this discovery,

a) if the time of detection of the death is known and if the death was detected in a medical facility

1. the intensive care unit,

2. the anaesthesiology and resuscitation department,

3. the operating room,

4. the admission department of the hospital.

b) if death has been determined following unsuccessful resuscitation.

(5) Brain death is established if

a) the patient is in a condition that would allow a diagnosis of brain death to be considered

b) clinical signs of the patient's brain death can be demonstrated, on the basis of which a diagnosis of brain death can be made, supplemented by an examination confirming the irreversibility of the brain death.

(6) The conditions on the basis of which a diagnosis of brain death can be considered, the clinical signs of the patient's brain death on the basis of which the diagnosis of brain death can be determined, the examinations proving them and the examinations confirming the irreversibility of brain death are listed in the Annex to this Act.

(7) The Ministry shall determine by decree the data required for the characterisation of a deceased donor and for the characterisation of organs from a deceased donor, the requisites in accordance with protocol on the determination of death, the specialized competence of the doctors detecting death and the doctors carrying out examinations confirming the irreversibility of death. The Ministry may lay down by decree more detailed conditions on the manner of carrying out examinations proving death, examinations confirming the irreversibility of circulatory arrest or brain death and the conditions for their implementation.

§ 10a

Admissibility of collection from a foreign deceased donor

(1) A foreigner [9)], for whom the collection of tissues or organs may be assumed pursuant to this Act, can donate tissues or organs only if he or she holds a valid document of consent to post-mortem donation of tissues or organs issued by the competent authority of the State of which the foreigner is a citizen (hereinafter referred to as the "donor card").

(2) In the case of a foreigner who does not have a donor card and who can be expected to donate tissues or organs in accordance with this Act, the health care provider shall ask a person close to the foreigner, if he or she knows whether

a) the foreigner has not made a declaration of intent to oppose the post-mortem removal of tissues or organs,

b) the foreigner has consented to the donation of tissues or organs, if the principle of presumed dissent is applied in the State of which he or she is a citizen,

c) agrees to that person's post-mortem donation of tissues and organs.

(3) If the health care provider finds out in accordance with par. 2 that collection from a foreigner can be carried out, it shall ensure the fulfilment of the obligation pursuant to § 15 par.1.

(4) If the health care provider is unable to make an inquiry pursuant to par.2 directly with a person close to the foreigner referred to in par.2, the Coordination Centre for Transplantation, on the basis of his initiative, shall ask

a) the competent authority of the State of which the foreigner is a citizen for the information referred to in par.2 letter a),

b) the diplomatic representation or consular office of the State of which the foreigner is a citizen for a person close to the foreigner's contact.

The Transplant Coordination Centre shall immediately forward the contact details and the information obtained to the health service provider.

(5) If the facts ascertained pursuant to par.4 letter a) make it possible the donation from the foreigner, the health service provider shall find out from a person close to the foreigner whether he or she consents to the post-mortem donation of tissues and organs from this foreigner, and in case of consent shall at the same time ensure that the obligation pursuant to § 15 par.1 is fulfilled.

(6) A close person's statement and information from the competent authority of the State of which the foreigner is a citizen, pursuant to par.4 letter a) shall be written down in the medical documentation of the foreigner.

(7) If the health service provider does not receive information on the facts pursuant to par.2 or par. 4 and 5 within 72 hours or if a person close to the foreigner referred to in par.2 pursuant to § 15 par.1 cannot be informed, the conditions for the donation are not fulfilled.

§ 11

Inadmissibility of donation from a deceased donor

(1) Donation from a deceased donor is not carried out if:

a) the deceased person during his or her life, or the legal representative of the deceased person who was a person not fully independent, has demonstrably disagreed with the post-mortem donation of tissues and organs (§ 16),

b) it cannot be ruled out, on the basis of a medical fitness assessment, that the deceased person suffered from a disease or condition that could endanger the health or life of the recipient; the donation provider is responsible for assessing the medical fitness of the deceased organ donor; in the case of tissue donation, the medical fitness assessment of the deceased donor shall be in accordance with the Law governing human tissues and cells,

c) the deceased person cannot be identified.

(2) The assessing doctor shall write down in a minutes the assessment of the deceased donor's medical fitness specifying the scope of the assessment and a concluding on the deceased donor's eligibility or ineligibility for donation. This minutes, with the date of the assessment, signed by the assessing doctor, shall be an integral part of the deceased donor's medical records.

(3) More detailed conditions for the assessment of medical fitness and the scope of examination of a deceased organ donor shall be laid down by the Ministry by decree.

§ 12

Tissues and organs removed

(1) The doctor who carried out the tissue or organ donation shall write down the list of the collected tissues and organs and the purpose of their use in the donor's medical records.

(2) Health services providers involved in the removal of organs or tissues from a deceased donor and their transplantation shall promptly inform each other of any additional discovery about medical unsuitability of the deceased donor and shall also promptly inform the Coordination Centre for Transplants about that.

(3) Tissues collected according to the Law regulating the handling of human tissues and cells that have not been used for transplantation may only be handed over to a tissue bank for further examination, processing, preparation, preservation, storage and distribution.

§ 13

Autopsies

(1) An autopsy shall always be carried out on the body of a deceased person on whom a harvesting has been carried out in accordance with a special legal regulation. **[10])**

(2) The autopsy of the deceased person from whom the harvesting was carried out, shall be carried out as soon as possible so that in case of additional finding that he or she suffered from a disease or condition that could endanger the health or life of the recipient, his or her inability to donate can be considered.

(3) If the doctor examining the deceased suspects that the death occurred under unclear circumstances or in a violent manner, including suicide or homicide, donation may be carried out only on condition that the autopsy is conducted under a special legal regulation. **[11])** At the same time, it is necessary for the needs of further investigation to examine the removed tissue or organ and also the part of the body from which they were removed so that the result of the inspection can become part of the autopsy report.

(4) If the doctor who carried out the autopsy finds out on the basis of the results of this autopsy that the deceased person suffered from a disease or condition that could endanger the life or health of the recipient, he or she shall promptly warn the health care provider who carried out the tissue or organ removal. If, as a result of the autopsy, an additional medical examination of the deceased donor has been made and the organ or tissue removed from that donor has already been transplanted, the healthcare provider shall immediately take precautionary measures to avoid endangering the recipient's life or health or ensure that the recipient receives the necessary medical care. They shall immediately notify the Transplant Coordination Centre.

§ 14

Respect for the human body

When autopsies are carried out the body of the deceased person shall be treated with respect and all operations shall be carried out in such a way as to restore the body, as far as possible, to its original form.

Part 3

Communication of the intended collection to a close person and disagreement with the post-mortem collection

§ 15

(1) The attending physician of a patient, who may be expected to take tissues or organs in accordance with this Act, shall inform persons close to him in an appropriate manner, unless the patient has determined otherwise pursuant to § 19 (hereinafter the "designated person") of the donation option, provided that the person is interested in the patient and the patient has not demonstrably expressed a ban on communicating information about his/her health condition during his/her lifetime. If the patient referred to previously is a person not fully independent, the attending physician shall notify his legal representative and at the same time inform him on the possibility of expressing a demonstrable disagreement with the donation according to § 16 par.1 letter c). In this case, the condition of expressing concern in the patient does not apply. At the same time, the attending physician shall explain to the designated persons, or the legal representative, the scope and purpose of the intended procurement, while respecting the anonymity of the recipient. The designated persons or legal representatives shall have the right to ask questions, except for questions about the recipient. If the designated person or legal representative refuses the explanation referred to in the fourth sentence, the attending physician respects his refusal and writes down this fact in the patient's medical records.

(2) In the case of a deceased person, or a deceased person who lacks full legal capacity, who is expected to have tissues or organs removed in accordance with this Act, the information pursuant to par.1 shall be provided by the physician authorised by the statutory body of the health care provider.

(3) The physician shall include the information submitted pursuant to par.1 in the patient's medical documentation.

§ 16

(1) The removal from the body of a deceased person, or of a deceased person who lacks full legal capacity, shall be carried out only if he or she, or the legal representative, has not demonstrably expressed his disagreement during his or her lifetime. Disagreement shall be considered demonstrably expressed if:

a) the deceased person is registered in the National Register of Persons Disagreeing with Post-mortem Tissue and Organ Collection, or

b) the deceased person, during his or her lifetime, declares in the medical facility in front of the attending physician and one witness that he or she does not consent to the removal in the event of his death, or

c) the legal representative of a person who lacks full legal capacity declares in the medical facility in front of the attending physician and one witness that he/she does not consent to the donation; this declaration shall be made during the lifetime of the person who lacks full legal capacity, or even after the death of that person.

(2) The refusal to consent to the donation referred to in par.1 letter. b) c) shall become part of the patient's medical records without delay. This minutes shall be signed by the patient, the attending physician and the witness, and, if the patient is unable to sign due to his medical condition, by another witness. In the case of a person who lacks full legal capacity, the minutes shall be signed by his/her legal representative and the attending physician, or the doctor referred to in § 15 par.2. The minutes shall also state the date and time at which the declaration was made. A copy of the minutes of the declaration referred to in par.1 letter a) b) or a copy of the minutes of the declaration made in the event of death pursuant to par.1 letter a) c) shall be sent the health care provider to the National Register of persons who do not consent to the post-mortem collection of tissues and organs within 3 days of its compilation.

(3) If it has not been proven that the deceased person has demonstrably disagreed with the post-mortem donation during his lifetime, he or she shall be presumed to have consented to the donation.

ARTICLE III

RECIPIENT

§ 17

(1) The selection of the most suitable organ recipients is based on the principle of medical urgency and equality of waiting; in case of equality of medical urgency, the total time of registration in the National Register of Persons Awaiting Organ Transplantation shall also be taken into account.

(2) The provisions of par.1 shall not apply to the procurement of organs from living donors.

(3) The recipient or his legal representative shall give informed written consent to the transplantation, on the basis of complete instructions provided to the recipient by the doctor assessing his medical fitness, or by a doctor carrying out the transplantation; when providing full instructions and expressing informed written consent, the provisions of § 7 shall apply mutatis mutandis. If it is not possible to obtain the written consent or the consent of the legal representative due to the health conditions of the recipient and if transplantation is an urgent procedure necessary to save the recipient's life or health, this consent shall be presumed. The reasons for not obtaining consent according to the previous sentences shall be written down in the recipient's medical documentation.

(4) Data on the donor's health related to the donation shall also be part of the recipient's medical documentation. Medical records containing data on the donor's health shall be kept in such a way as to preserve the anonymity of the donor.

ARTICLE IV

NATIONAL HEALTH REGISTERS RELATED TO TRANSPLANTATIONS

§ 18

(1) The National Health Registers [12] shall include the National Register of Persons Disagreeing with Post-mortem Tissue and Organ Donation, the National Register of Organ Donors, the National Register of Persons Awaiting Organ Transplantation and the National Register of Organ Transplants. These registers shall be established by the Ministry in accordance with a special legal regulation. [12]

(2) A special legal regulation shall apply to the maintenance of registers, the collection of data therein and the handling of such data, [12] , [13] unless this Act provides otherwise.

(3) The tasks related to the management of the National Register of organ donors, the National Register of people awaiting Organ Transplantation and the National Register of Organ Transplants shall be carried out under a special legal regulation [13] by the Transplantation Coordinating Centre (§ 25), which is responsible for personal data held in these registers. The tasks related to the management of the National Register of Persons Disagreeing with Post-mortem Tissue and Organ Donation shall be carried out by the Institute of Health Information and Statistics of the Czech Republic (hereinafter referred to as the "Statistical Institute"). For the purposes of maintaining the registers, the Statistical Institute is the processor of personal data in accordance with a special legal regulation. [13]

(4) The name and surname, birth number and address of the person who does not consent to the post-mortem removal of tissues and organs and the necessary data on the extent of the disagreement shall be entered in the National Register of Persons Disagreeing with Post-mortem Tissue and Organ Donation. The National Register of Organ Donors and the National Register of Persons Awaiting Organ Transplantation shall contain the necessary identification data of the donor, the persons awaiting organ transplantation, the persons who have undergone the transplant and the necessary data on the health status of these persons. Details on the scope and content of mandatory data entered into the National Register of Persons Disagreeing with Post-mortem Tissue and Organ Collection, the National Register of Organ Donors,[12] shall be determined by a decree of the Ministry. The Ministry may also determine by decree the set of data to be transmitted by the Centre for the Search for Hematopoietic Cell Donors from the Register of Potential Hematopoietic Cell Donors to the National Health Information System. [12]

(5) For the purpose of performing the tasks

a) the National Register of Organ Donors defines as a donor also a donor of tissue intended for direct transfer into the recipient's body,

b) the National Register of Persons Awaiting Organ Transplantation defines as a person awaiting transplantation also a person awaiting tissue transplantation intended for direct transfer into the recipient's body,

c) the National Register of Organ Transplants defines as a transplantation also a tissue transplant intended for direct transfer into the recipient's body.

ARTICLE V

OBLIGATIONS OF HEALTH SERVICE PROVIDERS IN THE PROVISION OF HEALTH SERVICES IN CONNECTION WITH TISSUE AND ORGAN DONATION AND TRANSPLANTATION

§ 19

Cooperation in providing data from basic registers and other information systems of public administration

(1) The Transplantation Coordinating Centre and the Statistical Institute shall use the following reference data from the population register for the performance of tasks in the management of national health registers pursuant to this Act:

a) surname,

b) name or names,

c) residence address, or the address to which documents are to be delivered pursuant to a special legal regulation,

d) date, place and district of birth and, in the case in which the person concerned was born abroad, date, place and State where he or she was born,

e) date, place and district of death and, in the case of death of the person concerned outside the territory of the Czech Republic, date of death, place and State in whose territory the death occurred; if there is a court decision declaring the person concerned dead, the date which is indicated in the decision as the date of death or, according to the circumstances, the date on which he or she did not survive, and the date on which this decision takes legal effect.

(2) The Transplantation Coordinating Centre and the Statistical Institute shall use the following reference data from the information system of population registration for the performance of their tasks in the administration of national health registers pursuant to this Act:

a) name, or names, surnames, maiden name,

b) date of birth,

c) sex,

d) place and district of birth and, in the case of a citizen who was born abroad, the place and State where the citizen was born,

e) birth number (ID-card)

f) permanent residence address, or the address to which the documents are to be delivered as well pursuant to a special legal regulation,

g) beginning of permanent residence, or date of cancellation of permanent residence and date of termination of permanent residence in the territory of the Czech Republic,

h) date, place and district of death; in the case of the death of a citizen outside the territory of the Czech Republic, date of death, place and State in whose territory the death occurred,

i) date stated in the court decision declaring the person dead as the day of death or, according to the circumstances, the date on which he or she did not survive, and the date on which the decision of the court declaring the person takes legal effect.

(3) The Transplantation Coordinating Centre and the Statistical Institute shall use the following reference data from the information system of foreigners for the performance of tasks in the administration of national health registers pursuant to this Act:

a) name, or names, surnames, maiden name,

b) date of birth,

c) sex,

d) place and State where the foreigner was born; if he or she was born in the Czech Republic, place and district of birth,

e) birth number (ID-card),

f) permanent residence address in the territory of the Czech Republic, or address to which documents are to be delivered pursuant to a special legal regulation,

g) date, place and district of death; in the case of a foreigner's death outside the territory of the Czech Republic, State in which the death occurred,

h) date stated in the court decision declaring the foreigner's death as the day of death, or as the day on which the foreigner did not survive.

(4) The Transplantation Coordinating Centre and the Statistical Institute shall use the following reference data from the register of birth numbers for the performance of tasks in the administration of national health registers pursuant to this Act:

a) birth number (ID-card),

b) in case of change of birth number, original birth number,

c) name, or names, surnames, or birth surname of the holder of the birth number,

d) date, place and district of birth and, in the case of a holder of a birth number born abroad, place and State in whose territory he or she was born.

(5) Among the data referred to in par.1 to 4, only such data necessary for the fulfilment of the task may be used in a specific case. Data which are held as reference data in the population register shall be used from the information system of population registration or the information system of foreigners only if they are in a form prior to the current state.

§ 20

Respecting anonymity between donors and recipients and the information obligation of health care providers

(1) Health service providers are obliged to maintain anonymity of

a) the deceased tissue or organ donor to the recipient,

b) the living tissue or organ donor to a person referred to in § 3 par.2, if the donor so wishes,

c) the living renewable tissue donor, unless he or she is a person referred to in § 3 par.2.

(2) The health service provider carrying out tissue removal and transplantation, the transplantation centres and the Transplantation Coordinating Centre shall write down and maintain the birth number in order to identify the donor. For this purpose, the health care provider shall be entitled to require the submission of a document stating the birth number. The donor's birth number shall be kept for traceability purposes.

(3) Health care providers shall promptly inform the relevant transplant centre about possible organ donors (§ 22).

§ 21

Healthcare provider carrying out tissue procurement and tissue transplantation

In addition to the obligations arising from a special legal regulation **[15]),** the health care provider carrying out tissue procurement and tissue transplantation, which is not a transplant centre (§ 22), shall also:

a) report persons who have donated organs to the National Register of Organ Donors,

b) report transplantations of tissues intended for direct transfer into the recipient's body to the National Register of Organ Transplants,

c) in the case of tissue donation, provide the data requested by the Transplantation Coordinating Centre,

d) obtain information from the National Register of Persons Disagreeing with the Post-mortem Donation of Tissues and Organs in order to retrieve deceased donors, and at the same time respect the expressed disagreement with the donation,

e) verify other methods of demonstrable expression of disagreement with the post-mortem donation foreseen in this Act and respect such expressed disagreement,

f) keep procurement and transplantation documentation and write down the collected tissues or organs in the report on the collected tissues and organs,

g) ensure monitoring of the health status of living donors and recipients,

h) have an import or export permit (§ 26a to § 26g).

§ 22

Transplantation centre

(1) The transplantation centre shall be a health care provider who has been granted the status of a highly specialized care centre [22] **)** and who shall, on that basis, collect and transplant haematopoietic stem cells, organs and tissues that have not been handed over to a tissue bank pursuant to § 12 par.3. The transplantation centre shall fulfil the obligations pursuant to § 21 and shall also:

a) report persons indicated for tissue and organ transplantation to the National Register of Persons Awaiting Organ Transplantation,

b) carrying out tissue and organ transplantation exclusively to recipients registered in the National Register of Persons Awaiting Organ Transplantation,

c) cooperate with the Transplantation Coordinating Centre in selecting the most suitable organ recipients,

d) after receiving the information pursuant to § 20 par.3, determine whether the conditions for collection are fulfilled (§ 10 to § 11),

e) after determining whether the conditions for collection have been fulfilled, inform the Transplantation Coordinating Centre about a possible donor,

f) verify that an assessment of the donor's medical fitness has been carried out and written down, including the completion of the organ and donor characterization,

g) determine whether the conditions of preservation and transport of the delivered organs have been complied with,

h) keep documentation on procurement and transplantation and write down the handling of harvested organs in the report on the final designation of harvested organs,

i) report any serious adverse reactions to the Transplantation Coordinating Centre and the health care provider carrying out tissue procurement and transplantation or to other transplantation centre;

j) report the actions taken to address serious adverse reactions to the Transplantation Coordinating Centre.

(2) The transplantation centre shall also

a) develop and maintain a quality and safety assurance system for all stages of the process from donation to transplantation,

b) for traceability purposes, use a donor and recipient identification system through which each donation, each associated organ and each associated recipient can be identified; the data needed to ensure traceability shall be kept by the transplantation centre for at least 30 years,

c) implement working procedures for the collection, preservation, packaging and labelling of organs,

d) implement working procedures for the reporting, investigation, registration and transmission of information on serious adverse reactions which may affect the quality and safety of organs, and which may be caused by the investigation, characterisation, procurement, preservation and transport of organs, as well as information on any adverse reactions observed during or after transplantation that may be related to these activities,

e) implement working procedures ensuring the integrity of the organ during the transfer and the appropriate time of the transfer,

f) ensure that healthcare professionals directly involved in the process from donation to transplantation or disposal of an organ or tissue are suitably qualified or trained.

(3) The transplantation centre carrying out hematopoietic stem cell transplantation shall fulfil the obligations pursuant to § 21 letter c) and g) and cooperate with the centres for the search for hematopoietic cell donors (§ 24) in the selection of the most suitable unrelated potential hematopoietic cell donors and make the final selection of a suitable hematopoietic cell donor for a specific recipient.

§ 22a

Tissue and organ management protocol

Healthcare professionals involved in the procurement or transplantation of tissues and organs shall write down the handling of the harvested tissues or organs in a minutes attached to the harvested tissue or organ. This minutes shall include in particular the date and place of procurement and the final destination of

the tissue or organ collected. If the harvested tissue or organ is used for transplantation, the date, place and person who was transplanted shall be written down in the report. If the harvested tissues and organs have been judged unsuitable for transplantation, the reason why they have been considered unsuitable and how they are to be further handled shall be written down in the minutes. The health care provider shall ensure that the report is sent to the Transplantation Coordinating Centre within 7 days from the date on which the tissue or organ has been removed.

§ 23

Tissue bank

(1) The Tissue Bank is intended to ensure the procurement, further processing, examination, preservation, storage and distribution of tissues for transplantation; these activities are carried out in accordance with the Human Tissues and Cells Act.

(2) Tissue Banks shall also

a) cooperate with the Departments of Forensic Medicine and Pathology, Departments of Gynaecology and Obstetrics of the health care providers, transfusion service facilities and health care providers referred to in § 21 and § 22 in the organization of tissue procurement;

b) use information of the National Register of Persons Disagreeing with Post-mortem Tissue and Organ Donation and the National Register of Organ Donors,

c) manage registers of tissues collected and transplanted, tissues examinations carried out, collected tissue grafts in stock and grafts issued to the transplant unite.

§ 24

Hematopoietic Cell Donor Retrieval Centre

(1) The Hematopoietic Cell Donor Retrieval Centre is designed for the retrieval of unrelated hematopoietic cell donors, their examination and the methods of hematopoietic stem cell transplantation. A hematopoietic stem cell retrieval centre shall be established only with the Ministry's approval. [17])

(2) Hematopoietic Cell Donor Retrieval Centre shall

a) manage documentation on the performed examinations of potential hematopoietic stem cells donors and on the methods of hematopoietic stem cell transplantation,

b) manage a register of potential hematopoietic stem cells donors,

c) provide, at the request of the health service provider, information on potential hematopoietic stem cells donors in order to assess their suitability for a particular recipient,

d) ensure and coordinate international cooperation in the exchange of hematopoietic stem cells designed for transplantation,

e) ensure that the public is informed about the importance and possibilities of hematopoietic stem cell donation in order to recruit new donors and ensure that potential voluntary hematopoietic stem cell donors are informed about the facts related to voluntary donation,

f) ensure the assessment of the potential donors' medical fitness prior to their inclusion in the Register of Potential Hematopoietic Stem Cell Donors,

g) search in the Register of Potential Hematopoietic Stem Cell Donors for suitable unrelated hematopoietic stem cell donors for a specific recipient,

h) monitoring the health status of unrelated donors after donation,

i) ensure further examinations to the donor.

(3) For the purpose of maintaining the Register referred to in par.2 letter b), the Hematopoietic Cell Donor Retrieval Centre shall establish and monitor an information system to identify potential hematopoietic stem cell donors. Data on potential donors shall be kept for as long as the donors are in the Register, but for at least 30 years from the date of hematopoietic stem cell donation. The potential donor's consent to keep his personal data in the Register shall be put in writing.

(4) By 1 March each year, the Hematopoietic Cell Donor Retrieval Centre shall prepare an annual report on the activities of the Hematopoietic Cell Donor Retrieval Centre of the previous year. It shall publish the annual report by that date at the latest in a manner allowing remote access and submit it to the Transplantation Coordinating Centre.

§ 25

Transplantation Coordinating Centre

(1) The Ministry of Health shall establish a Transplantation Coordinating Centre for the performance of the tasks referred to in par.2. When establishing the Transplantation Coordinating Centre, the Ministry shall proceed in such a way as to maintain its independence from transplantation centres in terms of space, material, technical equipment and location.

(2) The Transplantation Coordinating Centre shall perform the following tasks:

a) to maintain the National Register of Persons Awaiting Organ Transplantation;

b) to maintain the National Register of Organ Donors;

c) to maintain the National Register of Organ Transplants;

d) to coordinate the procurement and transplantation teams of individual transplantation centres;

e) to select the most appropriate recipients for the organs collected and for the tissues to be transferred directly to the recipient's body; the selection shall be made exclusively from the National Register of Persons Awaiting Organ Transplantation on the basis of a written predefined allocation algorithm;

f) to coordinate the activities of the Hematopoietic Cell Donor Retrieval Centre;

g) to ensure and coordinate international cooperation in the exchange of organs designed for transplantation (§ 26);

h) to cooperate with the Ministry to ensure the quality and safety of organ transplants;

i) to performing tasks related to the exchange of organs between member States of the European Union (hereinafter referred to as a "Member State") and between European States and other countries;

j) to enter into a written agreement with European organ exchange organizations, provided that such organizations ensure compliance with the requirements set out in this Act;

k) to prepare other working procedures;

l) to perform other tasks determined by the Ministry.

(3) The Transplantation Coordinating Centre shall include a central monitoring unit, which processes aggregated data on donations, transplants and their results for each year and submit a report on it to the Ministry no later than 31 March of the following year.

(4) The Ministry shall determine by decree a set of requirements for the establishment of working procedures to ensure the system of organ quality and safety for the organ collection, preservation, packaging, labelling and transport and traceability, and for accurate, rapid and verifiable reporting of serious adverse reactions and their procedures.

ARTICLE VI

INTERNATIONAL COOPERATION

§ 26

(1) The international exchange of tissues and organs for transplantation shall only be permitted if its purpose is to find the most suitable recipient or to rescue a waiting person whose life is in imminent danger and provided that the tissues and organs meet quality and safety requirements, and that their traceability is ensured.

(2) The organ donation abroad within the framework of an international organ exchange pursuant to par.1 shall be possible only if a suitable person waiting for transplantation is not registered in the National Register of Persons Waiting for Transplantation in the Czech Republic, or if the procedure is carried out within the framework of membership in international transplantation organizations.

(3) Tissues and organs may be accepted for transplantation from abroad within the exchange of tissues and organs pursuant to par.1 only if the collection was performed by a qualified health service provider and in a manner that is in accordance with the applicable legislation of the country of origin. It shall be demonstrated that the donor's medical fitness has been assessed prior to the collection and that the donor's medical records related to the collection is traceable.

(4) The conditions of hematopoietic stem cell transplantation in the context of international cooperation shall be laid down by a decree of the Ministry.

§ 26a

(1) The Ministry shall issue an import or export permit for the import of tissues into the Czech Republic, for their export from the Czech Republic or for the import or export of organs within the framework of an international exchange pursuant to § 26, Par.1 and 2 (hereinafter referred to as "import or export of tissues or organs"). The Ministry shall decide on the application for an import or export permit within 90 days from the date of its submission.

(2) The application for the grant of an import or export permit shall contain, in addition to the general requirements pursuant to the Administrative Procedure Code,

a) the Combined Nomenclature of the Common Customs Tariff's code and the name identifying the specified tissues or organs designed to import or export of which an import or export authorization is sought, as laid down in a Government Decree,

b) the proposed number of tissues or organs in pieces or cells in millilitres,

c) the proposed period of validity of the import or export permit,

d) the purpose of the import or export,

e) the name of the State or States of origin of the tissues or organs in the case of import, the name of the State or States of destination of the tissues or organs in the case of export.

(3) The applicant shall attach to the application for the grant of an import or export permit

a) an extract from the Commercial Register or an officially certified copy of the deed of incorporation,

b) enumeration and specification of the types of tissues or organs exported or imported,

c) in the case of export, a document or an officially certified copy thereof issued by a public authority certifying that it is a health service provider authorized to carry out tissue or organ procurement.

(4) In the event that the import of an organ into the Czech Republic or the export of an organ from the Czech Republic is necessary to save life in less than 90 days, the Ministry shall approve such import or export afterwards. An application for such additional approval of an organ import into the Czech Republic or organ export from the Czech Republic shall be submitted to the Ministry immediately after its implementation.

§ 26b

(1) The decision on granting an import or export permit shall contain, in addition to the general requirements pursuant to the Administrative Procedure Code,

a) the registration number of the import or export permit,

b) the Combined Nomenclature of the Customs Tariff's code and the name identifying the tissues or organs for the import and export of which the import or export authorization is sought,

c) the period of validity of the import or export authorization, including the number of organs, tissues or cells in millilitres that may be imported or exported;

d) the name of the State or States of origin of the tissues or organs in the case of import, the name of the State or States of destination of the tissues or organs in the case of export,

e) instructions on the obligation to return a copy of the import or export permit within 10 working days after its expiry (§ 26e),

f) the purpose of the import or export,

g) Annexes to the Decision; each annex shall define space for registration of the identification data of the healthcare provider who collected the tissue or organ and for customs authorities' registration on the use of the granted import or export authorization (quantity, date, stamp, signature); the number of annexes corresponds to the number of maximum imports or exports authorized in accordance with point c).

(2) The Ministry shall grant an import or export permit for a maximum period of 12 months.

§ 26c

(1) The Ministry shall not grant an import or export permit if the security interests of the Czech Republic are not granted (possibility of risk to the health and life of the population).

(2) The Ministry shall withdraw an import or export permit if

a) the import or export authorization was granted on the basis of false or incomplete information,

b) the conditions or extent specified therein have not been complied with,

c) the security conditions of the Czech Republic are not met.

(3) An appeal against a decision to withdraw an import or export permit pursuant to par.2 shall not have suspensory effect.

(4) The Ministry and the General Directorate of Customs shall provide each other with data concerning an import or export permit, to the extent of the data specified in the decision pursuant to § 26b. They shall promptly inform each other of facts relevant to administrative proceedings concerning the granting, non-granting or withdrawal of an import or export permit pursuant to this Act, check compliance with the conditions set out in import or export permits and impose administrative penalties.

§ 26d

(1) The import or export of a tissue or organ pursuant to § 26a par.1 and the import or export of an organ pursuant to § 26a par.4 may only be carried out with the consent of the Transplantation Coordinating Centre, which may give its consent

a) to a specific export if no suitable waiting person is registered in the National Register of Persons Awaiting Organ Transplantation in the Czech Republic,

b) to a specific import if the organ or tissue is designed for a specific recipient.

(2) The Transplantation Coordinating Centre shall cooperate with the General Directorate of Customs in order to ensure traceability.

§ 26e

An import or export license shall not be transferable or assignable. The health service provider, who has been granted an import or export permit, shall return this permit to the Ministry within 10 working days of its exhaustion or expiry, including minutes on its use by the customs authorities and a list of foreigner persons approved by the State authority to which organs or tissues were exported from the Czech Republic or from which organs or tissues were imported into the Czech Republic.

§ 26g

The provisions of § 26a to § 26d shall apply mutatis mutandis to the import or export of tissues or organs between the Czech Republic and the Member States.

ARTICLE VII

OTHER DONATION, COLLECTION AND TRANSPLANT ACTIVITIES

§ 27

Ministry

a) The Ministry shall ensure that the public is informed about the importance and possibilities of tissue and organ donation, especially haematopoietic stem cell donation, about how to express disagreement with post-mortem donation and about the importance of transplantation; in doing so, it shall cooperate with other administrative authorities and local self-government bodies, health insurance companies, health service providers, professional organizations in the health sector and other bodies and institutions.

b) At the request of the European Commission or another Member State, the Ministry shall inform

1. on the conditions which, pursuant to legal regulations, must be met by a health service provider who intends to provide health services pursuant to this Act,

2. on the activities of health care providers performing procurement and transplantation pursuant to this Act, on the total number of living and deceased donors, on the type and number of transplanted or disposed organs, including the provision of a report pursuant to § 25 par.3.

§ 28

Prohibition of financial gain or other benefits and trade in tissues and organs

(1) The human body and its parts shall not as such be a source of financial gain or other benefits; this does not affect the provisions of § 28a to § 28d.

(2) Neither the donor nor any other person shall make any claims against the recipient.

(3) Advertising and publicity for the purpose of soliciting or offering organs are prohibited. The procedure pursuant to § 27 shall not considered advertising.

(4) Trafficking in tissues and organs collected for the purpose of transplantation is prohibited.

§ 28a

Funeral allowance

(1) A person who has arranged a funeral for a deceased donor who has undergone organ harvesting shall be entitled to a contribution of CZK 5,000 towards the costs related to the organization of the funeral.

(2) In addition to the general requirements pursuant to the Administrative Procedure Code, the application for payment of the funeral costs shall include

a) proof of payment of the funeral costs,

b) data relating to the deceased donor, namely name or names, surname, date of birth and date of death,

c) name and address of the health service provider in which the organ was collected,

d) indication of how the amount is to be paid.

(3) If the application is not submitted to the Ministry within 12 months from the date of the funeral, the right to a contribution to the funeral costs expires.

(4) The transport of the body of the deceased donor from the place of autopsy to the place of burial shall be covered by the recipient's health insurance company.

§ 28b

Compensation provided to a living organ donor

(1) The organ donor shall be entitled to reimbursement of expenses reasonably and demonstrably incurred (hereinafter referred to as “reimbursement of expenses”) and the difference between the lost earnings and the wage, salary or remuneration and the sickness benefit received from sickness insurance. The provision of health services required for such collection shall be also provided (hereinafter "lost earnings").

(2) In addition to the general requirements pursuant to the Administrative Procedure Code, the application for payment of compensation for expenses and lost earnings shall include,

a) the date of which the organ was harvested and the period during which health services related to the organ harvesting were provided,

b) the name and address of the transplantation centre that performed the procurement and the address of the health service provider at whose medical facility the donor received health care services related to the procurement of the organ,

c) a document certifying the amount of expenses incurred and the amount of lost earnings, or a certified copy thereof,

d) a certified copy of termination of the temporary incapacity for work due to the collection; a person without a document of temporary incapacity for work shall provide a written statement from the health service provider as to the period during which he or she was unable to perform the activity for which he or she is claiming compensation for lost earnings.

(3) The Ministry shall ask the transplantation centre that performed the procurement and the health care provider, which provided health services to the donor, to confirm the facts referred to in par.2 letter b) and to state whether the claimed expenses and lost earnings correspond to the period during which the donor had the organ harvested and health services provided. The transplantation centre and the health care provider shall provide the required information within 10 days of the delivery of the request.

(4) If the request for reimbursement of expenses or lost earnings is not submitted within 24 months from the date of the donation, the right to reimbursement shall expire.

(5) Donors shall be reimbursed for expenses and lost earnings in the proven amount, but not more than twice the average wage in the national economy as announced and published by the Ministry of Labour and Social Affairs in the Collection of Laws for Employment Purposes [23]) . Reimbursement of expenses shall not include reimbursement of the donor's travel expenses paid in accordance with the law governing public health insurance.
(6) The health care provider shall ensure that the donor is informed of the possibility of claiming reimbursement and lost earnings prior to the procurement of the organ and, for this purpose, submit an application in accordance with par.2. A minutes of this information, signed by the health care professional documentation shall become part of the donor's medical records.

§ 28c
The Ministry shall decide on the contribution to the funeral expenses pursuant to § 28a or on the compensation provided pursuant to § 28b. In the case of a procedure pursuant to § 28b par.3, the time limit for issuing a decision shall be extended by 30 days.

§ 28d
The Ministry may entrust the Transplantation Coordinating Centre with the exercise of competences pursuant to § 28a to § 28c.

ARTICLE VIII
OFFENSES

§ 29
(1) A person commits an offense by violating the prohibition pursuant to § 28 par.3.
(2) The health service provider commits an offense by:
a) failing to fulfil or breaching any of the obligations pursuant to § 3, § 4, § 6 par.1 or 4, § 8 par.1, § 10 par.1, 2 or 4, § 11, § 13, § 16 par.1 or 2, § 20 par.1 or 3, § 21, § 23 par.2, § 25 par.2, § 26 par.1 to 3 or § 28 par.1, 3 or 4,
b) failing to fulfil or breaching any of the obligations pursuant to § 10a, § 22, § 24 par.2 to 4 or § 26d par.1,
c) failing to fulfil or breaching any of the obligations pursuant to § 6 par.3, § 7 par.1 to 3, 6 or 7, § 8 par.2, § 9 par.1, § 12, § 14, § 15 par.1, § 16 par.3, § 22a or § 25 par.3,
d) importing or exporting organs without an import or export authorization; or
e) importing or exporting organs in violation of the import or export authorization granted.
(3) The offence is punishable by a fine up to
a) CZK 50,000, if it is an offense pursuant to par.2 letter c),
b) CZK 100,000, if it is an offense pursuant to par.2 letter a) or b),
c) CZK 500,000, if it is an offense pursuant to par.1,
d) CZK 1000000, if it is an offense pursuant to par.2 letter e),
e) CZK 5000000, if it is an offense pursuant to par.2 letter d).

§ 30
(1) Offenses pursuant to this Act shall be dealt with by the regional authority, with the exception of offenses pursuant to § 29 par.b), which shall be dealt with by the Ministry. The regional authority that has granted the health service provider the authorization to provide health services[1]) shall be competent to deal with offences pursuant to § 29 par.2 letter a) and c) to e).
(2) The fine shall be levied by the administrative authority that imposed it.
(3) An administrative authority which has imposed a fine for an offence to a health service provider shall send a copy of the decision of the offence pursuant to this Act to the health insurance company with which the health care provider has a contract.

ARTICLE IX

COMMON AND TRANSITIONAL PROVISIONS

§ 31

When the term "donor" or "donation" is used in this Act, the general legal regulations governing donation and related requirements shall not apply. **[20])**

§ 31a

Uterine transplantation and related procedures may be performed pursuant to this Act if the Ministry recognizes uterine transplantation as a standard method in clinical practice under the Specific Health Services Act.

§ 32

(1) Medical facilities performing procurement and transplantation, transplantation centres, tissue banks and hematopoietic stem cell donors retrieval centres and parts of national health registries (§ 18) shall comply with the conditions set out in this Act no later than 2 years from the date of entry into force of this Act.

(2) The Ministry shall publish the establishment of the National Register of Persons Disagreeing with the Post-mortem Donation of Tissues and Organs and the method of registration of citizens in this register in order to ensure that these facts are made as widely known as possible. Pending the establishment of the register, the determination of opposition to the post-mortem donation shall be carried out in accordance with the existing legal regulations, except for cases where a citizen has expressed his or her demonstrable opposition in accordance with § 16 par.1 letter b).

PART THREE

Amendment to the Public Health Insurance Act

§ 34

Act N. 48/1997 Sb. on Public Health Insurance and on Amendments and Supplements to Certain Related Acts, amended by Act N. 242/1997 Sb., Act N. 2/1998 Sb., Act N. 127/1998 Sb., Act N. 225/1999 Sb., Act N. 363/1999 Sb., Act N. 18/2000 Sb., Act N. 132/2000 Sb., Act N. 155/2000 Sb., Judgment of the Constitutional Court N. 167/2000 Sb., Act N. 220/2000 Sb., Act N. 258/2000 Sb., Act N. 459/2000 Sb., Act N. 176/2002 Sb. and Act N. 198/2002 Sb., is amended as follows:

1. In § 13 par.2 letter a) including footnote n. 23a) states:

" **(a)** outpatient and inpatient medical care (including diagnostic care, rehabilitation, care for the chronically ill and healthcare for the organ and tissue donor related to their procurement); [23a)]

[23a]) Act N. 285/2002 Sb., on donation, procurement and transplantation of tissues and organs and on the amendment of certain acts (Transplantation Act). ”.

2. In § 13 par.2, new letter e) is inserted after letter d):

" **(e)** procurement and necessary handling of tissues or organs designed for transplantation (preservation, storage, processing and examination); [23a)] ".

The existing letters e) to j) are referred to as letters f) to k).

3. In § 13 par.2, new letters j) to l) are inserted after letter i), as follows:

" **(j)** the transport of the living donor to and from the place of donation, to and from the place of provision of healthcare related to the donation, and the reimbursement of travel costs,

k) transport of the deceased donor to and from the place of donation,

l) transport of collected tissues and organs (§ 36 par.4), ".

The existing letters j) and k) are referred to as letters m) and n).

4. A new section § 35a is inserted after § 35, as follows:

§ 35a

Tissue and organ transplantation

The healthcare for a living donor related to the donation of tissues and organs, the donation of tissues and organs from a living or deceased donor, the necessary handling of harvested tissues and organs, the transport of a living donor and reimbursement of his/her travel and transport costs shall be covered by the health insurance undertaking of which he/she is insured or the deceased donor was insured. "

PART SEVEN

Amendment to the Act on the Czech Medical Chamber, the Czech Dental Chamber and the Czech Pharmacy Chamber

§ 38

In Act N. 220/1991 Sb., on the Czech Medical Chamber, the Czech Dental Chamber and the Czech Pharmacy Chamber, amended by Act N. 160/1992 Coll., § 2 par.1 letter c) states:

" **(c)** assess and defend the rights and professional interests of its members,".

PART EIGHT

EFFICIENCY

§ 39

This Act shall enter into force on 1 September 2002, with the exception of Part Five par.3 and 5, which shall enter into force on 1 March 2003.

The transitional provision was introduced by Act No. 44/2013 Coll. Art. II

1. Data present in the Register of Hematopoietic Cell Transplantations performed before the date of entry into force of this Act shall be transferred by the Czech Haematological Society to the Jan Evangelista Purkyně Czech Medical Society in cooperation with the Transplantation Coordinating Centre within 12 months from the date of entry into force of this Act.

2. Health service providers shall start transmitting data on tissue donors, persons awaiting tissue transplantation and persons who have undergone tissue transplantation, including the necessary data on their health status, to the National Health Registers maintained pursuant to Act N. 285/2002 Sb. from the date of entry into force of this Act up to 6 months from the date of entry into force of this Act.

3. Reimbursement of expenses and lost earnings pursuant to § 28b of Act N. 285/2002 Sb., as amended from the date of entry into force of this Act, shall also be due to the living donor if the living donor was already incapacitated for work at the time of entry into force of this Act. In such a case, he or she shall be entitled to reimbursement from the date of incapacity for work.

4. The Hematopoietic Cell Donor Retrieval Centre shall prepare an annual report pursuant to § 24, par.4 of Act N. 285/2002 Sb., as amended from the date of entry into force of this Act, for the first time on 1 March 2013.

5. Transplant centres shall develop an internal system of quality and safety assurance for all stages of the process from donation to transplantation according to § 22 par.2 letter a) of Act N. 285/2002 Sb., as amended from the date of entry into force of this Act, within 12 months from the date of entry into force of this Act.

Klaus vr
Havel vr
in z. Rychetský vr

Annex to Act No. 285/2002 Coll.
Detection of death in cases of evidence of brain death

A.

A condition on the basis of which a diagnosis of brain death can be considered.

The condition on the basis of which the diagnosis of brain death can be considered is a condition in which:

a) there is no doubt about the diagnosis of structural brain damage or its irreversibility, and

b) the patient is in deep unconsciousness, on artificial lung ventilation, and it is excluded that he is involved in unconsciousness at the time of the examination due to

1. intoxication,

2. sedative and relaxing effects of drugs,

3. metabolic or endocrine disruption, or

4. primary hypothermia.

B.

Clinical signs of brain death and examination evidence.

1. The clinical signs of brain death on the basis of which a diagnosis of brain death can be made are:

a) pupillary areflexia,

b) corneal areflexia,

c) vestibulocochlear areflexia,

d) absence of any motor reaction to an alginic stimulus applied in the innervation area of the cranial nerves,

e) absence of a cough reflex or any immediate motor reaction to deep tracheobronchial suctioning,

f) permanent cessation of spontaneous breathing demonstrated by an apnoea test,

g) deep unconsciousness.

2. The examination for clinical signs of brain death (hereinafter referred to as 'examination for clinical signs of brain death') shall be carried out by 2 independent doctors according point 1.

3. In children under 1 year of age, examinations of clinical signs of brain death according to point 1 shall be carried out twice at intervals of at least 48 hours.

4. The reasons why the examination for clinical signs of brain death referred to in point 1 cannot be carried out shall be written down by the doctor examining the clinical signs of brain death in the death report.

C.

Examination confirming irreversibility of clinical signs of brain death

1. Examinations confirming the irreversibility of brain death are

a) angiography of cerebral arteries,

b) cerebral perfusion scintigraphy,

c) computed tomographic angiography,

d) transcranial Doppler ultrasonography; or

e) examination of auditory stem evoked potentials (BAEP).

2. On deceased persons with a clearly objective evidence of severe structural infratentorial lesion, only a clinical examination shall be performed

Footnotes

[1]) Act N. 372/2011 Sb., on health services and conditions for their provision (the Health Services Act).

[4]) Act N. 258/2000 Sb., on the protection of public health and on the amendment of some related regulations.

[7]) Section 124 paragraph 2 and Section 275 of the Labor Code.

[7a]) Act N. 296/2008 Sb., on ensuring the quality and safety of human tissues and cells intended for use in humans and amending the related acts (Act on Human Tissues and Cells).

[9]) Act N. 326/1999 Sb., on the stay of foreigners in the territory of the Czech Republic and on the amendment of certain acts, as amended.

[10]) Section 28 of Act N. 20/1966 Sb., as amended. Decree N. 19/1988 Sb., on the procedure in the event of death and burial, as amended by Act N. 256/2001 Sb.
[11]) Sections 105 and 115 of the Criminal Procedure Code.
[12]) Section 70 of Act N. 372/2011 Sb.
[13]) Act N. 101/2000 Sb., on the protection of personal data and on the amendment of certain acts, as amended.
[15]) For example, Act N. 372/2011 Sb., Act N. 296/2008 Sb., Act N. 48/1997 Sb., on public health insurance and on amendments to certain related Acts, as amended.
[17]) Section 70 paragraph 2 of Act N. 20/1966 Sb., as amended.
[20]) For example, the Civil Code, Act N. 357/1992 Sb., on inheritance tax, gift tax and real estate transfer tax, as amended.
[21]) Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23 / EC as regards procedures for the verification of equivalent quality and safety standards for imported tissues and cells.
[22]) Section 112 of Act N. 372/2011 Sb.
[23]) Act N. 435/2004 Sb., on employment, as amended.