

THE TRANSPLANTATION ACT

285/2002

on Donation, Removal and Transplantation of Organs and Tissues and on the Amendment of Some Acts

The Parliament has resolved upon the following Act of the Czech Republic:

PART ONE **DONATION, REMOVAL AND TRANSPLANTATION OF ORGANS AND TISSUES**

CHAPTER I **GENERAL PROVISIONS**

Article 1 Subject of the Act

This Act shall govern the conditions of donation, removal and transplantation of organs and tissues of human origin performed exclusively for the purpose of the providing of health care.

Article 2 Definitions

For the purpose of this Act it is understood:

- a) organ means an individual and vital part of a human body formed by structured order of different tissues, keeping its structure, venous supply and ability to perform physiological functions with a significant level of autonomy,
- b) tissues and cells mean building parts of a human body including remains resulting from surgical operations, as well as hematopoietic cells harvested from bone marrow, from peripheral and cord blood, excluding organs, blood and its components, reproductive cells, embryonic and foetal cells and organs, hair, nails, placenta and waste products of body metabolism (hereinafter only as “tissues”),
- c) potential donor means a patient in who, due to his/her health condition, death and possible removal of organs are presumed, or a body of a deceased person in whom death was confirmed and in whom possible removal of tissue or of an organ is presumed,
- d) donor means a person or a body of a deceased person from which removal of tissue or of an organ for transplantation purposes has been performed,
- e) death means an irreversible loss of function of the entire brain, including the brain stem,
- f) waiting patient means a person registered in the National Registry of Persons Waiting for an organ transplantation,
- g) recipient means a person who has been implanted tissue or an organ of human origin,

- h) removal means all procedures necessary for removal of human tissues or organs intended for transplantation, including examinations for the purposes of assessment of health suitability of the donor and his/her preparation for the removal,
- i) donation means procurement from a living donor including the health care provided to the donor for the purposes of recovery after performed removal,
- j) transplantation means a process leading to preservation of procured tissue or organ in stable quality for the purposes of implantation as well as implantation of tissue or organ in a recipient including all procedures in the course of preparation and conservation of tissues and organs.

CHAPTER II REMOVAL OF TISSUES AND ORGANS

Section 1 Removal of tissues and organs from living donors

Article 3

Acceptability of removal of organs and tissues from a living donor

- (1) If not stipulated otherwise below, removal of tissues and organs (hereinafter only as “the removal”) from a living donor may only be performed, if
 - a) it is performed exclusively for the medical benefit of the recipient,
 - b) at the time of removal there is no suitable tissue or organ from a deceased donor available, and there exists no other therapeutic method of comparable effectiveness,
 - c) the donor is a person capable of giving a free, informed and concrete consent (Article 7) and such a consent has truly been expressed by him/her, and
 - d) the tissues are regenerative or the organ is one of the functioning pair organs.
- (2) If not stipulated otherwise below, removal of organs from a living donor may be performed for the benefit of a recipient who
 - a) is a person having a close personal relationship to the donor, if the donor gave his or her free, informed and concrete consent in accordance with this Act (Article 7) with regard to this recipient,
 - b) is not a person having a close personal relationship to the donor, provided only that
 - 1. the donor has expressly made known the will to donate his/her organ to this recipient; such an explicit statement (hereinafter only as “the statement”) shall be executed in writing and the donor’s signature shall be witnessed by a notary public; the statement shall become an inseparable part of medical records of the donor,
 - 2. this donation has been approved by the Ethical Committee in accordance with Article 5, paragraph 5 a).
- (3) Removal of organs from a living donor may not be performed, if

- a) it can be reasonably presumed that the transplantation might gravely endanger the health or life of the donor,
- b) the donor is a person serving his/her sentence of imprisonment or being in custody or subject to preventive detention or to protective treatment, excepting the cases of donorship between children and parents, between siblings and between husband and wife, or
- c) on the basis of assessment of health capability of the donor, reasonable suspicion has arisen that the donor suffers from a disease or condition that might endanger health or life of the recipient. This does not apply to the cases when the risk posed to the recipient's health is outweighed by the transplantation saving his/her life. Terms and conditions of prevention of the human immunodeficiency virus infection shall be stipulated by a special legislation.

Article 4

Protection of minors, legally incompetent persons and persons who due to their current health state

are not able to consider all consequences of removal of a regenerative tissue to their health

- (1) From donors who are minors, persons with limited legal competence or legally fully incompetent persons (hereinafter only as “legally incompetent person”), or persons who have expressed their consent to the donation but, with regards to their current medical condition, it can be reasonably presumed that despite full advice that they did not, or could not, assess all consequences relating to removal of regenerative tissue for their own health (hereinafter only as the “person unable to express consent”), if not stipulated otherwise below, removal of regenerative tissue may only be performed provided if
 - a) there is no other suitable donor available, being able to give his/her explicit and concrete consent,
 - b) the recipient is donor's sister or brother,
 - c) the donation represents a possibility of saving the recipient's life,
 - d) a legal representative of the donor who is a minor or a legally incompetent person has given his/her consent with the donation in accordance with Article 7, Paragraph 4,
 - e) the Ethical Committee has approved this particular donation in accordance with Article 5, Paragraph 5, Letter b), and
 - f) the donor has not objected to the donation.
- (2) The provisions of paragraph 1, letters b) and c) do not apply to the donation of cells if such donation carries only a minor risk to the donor's health and life.

Article 5

The Ethical Committee

- (1) The Ethical Committee shall be an independent committee established and dissolved by the statutory body of a health care facility performing the removal of an organ from the donor to the benefit of the recipient who is not a person having a close relationship (see Article 3,

Paragraph 2, Letter b), or the removal of a regenerative tissue from minors, legally incompetent persons or persons not capable to express their consent (Article 4). The Ethical Committee may be established as a permanent body or as a committee set up for individual cases.

- (2) The Ethical Committee shall have at least 5 members; it shall consist of physicians, one clinical psychologist and a lawyer. At least two thirds of the Ethical Committee members may not be employed or have a similar working relationship to the health care facility referred to in paragraph 1. The chairman and other members of the Ethical Committee shall be appointed and recalled by the statutory body of a health care facility in which the Ethical Committee was established. When performing the activities of the Ethical Committee, the chairman and the members of the Ethical Committee shall not be bound by instructions of the statutory body of the health care facility, nor by the instructions of other senior employees of the health care facility. The members of the Ethical Committee may only be individuals with no personal interest nor involvement in the performance of the removal of
 - a) an organ to the benefit of the recipient who has no close personal relationship to the donor, and/or in transplantation of the organ,
 - b) regenerative tissue from a minor, from a legally incompetent person or from a person not capable to express his/her consent, and/or in transplantation of the tissue.
- (3) The members of the Ethical Committee shall keep confidential all the information which they learnt in connection with the performance of their activities, except the cases when information is shared with the consent of the donor, recipient or a legal representative of a minor or of a legally incompetent person or on the basis of relief of their compulsory secrecy. With the consent of persons mentioned in the first sentence information can be shared in such manner that no information about third persons can be revealed and that anonymity between the donor and recipient be observed (Article 20). Special legislation, stipulating rules and obligations of medical personnel in the course of providing medical care, shall be used for relief of the members of the Ethical Committee of their compulsory secrecy. Performance of activities of members of the Ethical Committee shall be considered other kind of activities performed in public interest when an employee is granted time off in the extent necessary, with his/her average income remuneration.
- (4) The meetings of the Ethical Committee shall be chaired by the chairman. The Ethical Committee shall take decisions by the majority vote of its members. In case of equal vote the vote of the chairman shall be decisive.
- (5) Based on a written application of the statutory body of the health care facility that established the Ethical Committee, the Committee shall provide its written approval or disapproval with the performance of the removal of
 - a) an organ to the benefit of the recipient who has no close personal relationship to the donor,
 - b) regenerative tissue from a minor, a legally incompetent person or a person not capable to express consent.

The provision of such a consent or objection shall be part of medical records of the donor, minor, a legally incompetent person or a person not capable to give his/her consent.

- (6) The application for an approval shall contain
 - a) information on the health condition of the donor, minor, a legally incompetent person or a person not capable to express his/her consent, being decisive for the decision about possible removal of regenerative tissue,
 - b) statement of a clinical psychologist on the capability of a minor, a legally incompetent person or a person not capable to give his/her consent, to express his/her opinion regarding removal, asked for by the physician evaluating health condition of such a person,
 - c) information on the health condition of the recipient of an organ or regenerative tissue,
 - d) a copy of complete information given to the donor and of the informed consent of the donor of the organ or of the legal representative of the donor (Article 7, Para 1 and 2) or, as the case may be, a statement of the minor or the legally incompetent person (Article 7, Paragraph 6),
 - e) a copy of complete information given to the person incapable to give his/her consent and the consent of this person,
 - f) a copy of the statement by the donor made under Article 3, Paragraph 2, Letter b), and
 - g) time limit within which the Ethical Committee is obligated to give its approval or disapproval of the performance of the removal of an organ from the donor or of regenerative tissue from a minor, a legally incompetent person or a person incapable to give his/her consent.
- (7) If necessary, the Ethical Committee can also invite the organ donor or a legal representative of a minor or of a person not capable to give his/her consent, or such a person (as the case may be) to take part in the discussions on providing approval or disapproval of organ removal. The Ethical Committee shall always invite to participate in the discussion
 - a) a minor or a legally incompetent person in case that the clinical psychologist indicated in his/her statement that such a person is capable to deliver his/her opinion regarding the removal,
 - b) a person not capable to express his/her consent,
 - c) a donor of the organ referred to in Article 3, Paragraph 2, Letter b); in this case the Ethical Committee, apart from medical reasons, shall also establish and assess the reasons leading the donor to donate his/her organ.
- (8) In case of approval given in accordance with Article 5, the Ethical Committee shall inspect the removal procedure and observation of the rights of the donor, minor, legally incompetent person or a person incapable to give his/her consent.
- (9) The Ethical Committee shall duly keep records on its activities, particularly written working procedures, lists of members including their professional qualifications, submitted applications and documents and minutes from sessions, reports and correspondence related to its activities and evaluation of applications for at least 10 years, these shall be kept in the health care facility in which the Committee has been established. Should the Ethical

Committee be abolished, the statutory body of the health care facility in which the ethical Committee has been established shall provide for due keeping of any such documents.

Article 6

Health state evaluation of a living donor

- (1) Prior to removal from a living donor his/her health capability to donate tissue or an organ shall be evaluated. For this purpose, medical examinations and procedures shall be performed in order to evaluate health condition of the living donor as well as possible risks in connection with the donation of an organ or tissue posed to the health and life of the donor. At the same time, proper procedures shall be determined so that health and life risks of the donor in connection with the removal of an organ or a tissue be eliminated in all possible ways, without endangering the quality and vitality of removed tissues or organs.
- (2) The health care facility performing the removal is responsible for evaluation of the health capability of the donor in order to establish whether he/she is able to donate organs. In case of donation of tissues the assessment of health capability of the donor shall be carried out in accordance with the Tissue and Cells Act.
- (3) The evaluating physician shall make records on the evaluation of the health capability of the donor stating the scope of the evaluation and the decision on capability or incapability of the donor to donation. This record duly signed by the evaluating physician and containing the date shall be an integral part of the medical records of the donor.
- (4) The health care facility that has performed the removal shall provide for a long-term follow-up care of the donor.
- (5) Detailed terms and conditions for the evaluation of the health capability and the scope of examination of a living donor of organs shall be laid down by a Regulation of the Ministry of Health (hereinafter only as “the Ministry”).
- (6) A donor or a legal representative of a minor or a legal representative of a legally incompetent person, should such a person be the donor, may ask another physician, who is not involved in the removal nor in further procedures connected with the transplantation, to assess health risks of the removal for the donating person. Such an assessment is not subject to conditions given in Paragraphs 1 thru 5.

Article 7

Complete information and consent

- (1) The physician evaluating health capability of a living donor is obligated to provide the donor with complete information on the purpose, nature and consequences of tissue or organ donation and on possible risks connected with it, including long-term risks. If the donor is a minor or a legally incompetent person such information shall be provided to his/her legal representative. The information given has to be understandable. The donor and the legal representative of a minor or the legal representative of a legally incompetent person has the

right to pose questions in the scope referred to in the first sentence, and the physician is obligated to answer them. Providing information on the rights and on protection of a donor stipulated by this Act shall be a part of the above information given.

- (2) The donor and the legal representative of a minor or the legal representative of a legally incompetent person may require that another witness be present when being given the information. The physician providing complete information shall inform them about this possibility in advance. The physician shall draw up a record on the providing of complete information containing its brief contents, and all the persons present shall provide their dated signature thereof. The record on provision of complete information given to the donor or the legal representative of a minor or the legal representative of a legally incompetent person shall be an integral part of medical records of the donor.
- (3) Immediately before the removal, the physician performing the removal is obligated to repeat complete information given in accordance with the conditions stipulated in paragraph 1.
- (4) The consent of the donor or of the legal representative of a minor or of the legal representative of a legally incompetent person given based on complete information in accordance with paragraph 1 shall be free, informed and concrete. It shall be provided in writing, shall bear a dated signature and shall be filed in medical records of the donor. Definition of the purpose of use shall be a part of a consent expressed in relation to removal of tissue.
- (5) The donor or the legal representative of a minor or the legal representative of a legally incompetent person may withdraw his/her consent at any time. The physician performing the removal shall respect such a withdrawal unless no irreversible procedures, the interruption of which would endanger the health or the life of the donor, have been performed in the course of the removal.
- (6) If minors or legally incompetent persons are able to understand in a sufficient extent the consequences of the performance or non performance of the removal for themselves or for recipients it is necessary that they are provided with complete information as well. If the person referred to in the first sentence expresses his/her disapproval of the donation this decision shall be respected.
- (7) In the event of a consent expressed in connection with tissue removal, the health care facility shall provide a copy of the consent and/or its change to the tissue facility the tissues are transferred to. The transferring health care facility shall confirm conformity of the consent with the original.

Article 8

Conditional removal from a living donor

- (1) A removal of an organ from a living donor may only be performed to the benefit of the person appointed by the donor (Article 3, Paragraph 2). If the event that a living donor of tissue made a removal of such tissue conditional to its donation to a particular person such a removal may only be performed to the benefit of such a person.

- (2) In the event that the tissue or organ removed cannot be implanted into an appointed person's body it is necessary, prior to the performance of the removal, to obtain the consent of the donor to use the tissue or organ for a different person. The reasons leading physicians to the decision that the tissue or organ cannot be implanted into the person appointed by the donor shall be stated in medical records of the donor and of the person appointed by the donor.

Article 9

Transplantation of tissue or organ removed for a purpose other than transplantation

- (1) If tissue or an organ were removed from a patient for a purpose other than transplantation, these can be implanted into a recipient only if the patient was informed about consequences and possible risks of the removal, and before or after the removal of tissue or of an organ has expressed his/her consent with their use for transplantation.
- (2) When providing information and obtaining the consent in accordance with paragraph 1, the provisions of Article 7 shall apply similarly.

Section 2

Organ and tissue removal from deceased donors

Article 10

Permissibility of removal from a deceased donor and conditions of confirmation of death

- (1) A removal from a deceased donor may be performed only in case that death has been detected. Should a removal from a deceased donor be performed in time shorter than 2 hours after detection of death such a removal may only be performed after execution of a protocol according to Paragraph 2. Physicians who certify death may not take part in the removal from a deceased donor, nor in the transplantation, nor may they be treating physicians of the possible recipient.
- (2) Detection of death of a possible donor shall always be performed by two duly qualified physicians examining the donor independently on each other. In the event of presumed removal to take place before 2 hours from the detection of death the death certification of a possible donor shall be recorded in a protocol that shall comprise an integral part of medical records of the donor. The protocol on confirmation of death shall be signed by the physicians who have certified the death. The protocol shall contain the following data:
 - (a) basic and subsidiary diagnoses of a deceased person,
 - (b) records of examinations performed, including documentary images,
 - (c) records of detected results of examinations,
 - (d) timeframes of examinations performed, time of irreversible cardiac arrest (if detected),
 - (e) necessary identification data of physicians certifying death and physicians performing examinations confirming brain death.

A template of the protocol on detection of death is attached in Appendix No. 1.

- (3) Death (Article 2, Letter e) is certified through confirmation of
 - (a) irreversible cardiac arrest,
 - (b) irreversible loss of function of the whole brain, including brain stem in the cases when functions of breathing or of blood circulation are maintained artificially (hereinafter only as “brain death”).
- (4) In the event of detection of death through certification of irreversible cardiac arrest a removal may be performed before 2 hours from such a detection if
 - (a) the time of detection of death is known, and the death was detected in a health care facility
 1. at the Intensive Care Unit,
 2. at the Anesthesiology and Resuscitation Ward,
 3. at an operating theater,
 4. at the out-patients admission department or the admission ward of a hospital,
 - (b) if death has been detected on the basis of an unsuccessful resuscitation, which failed in restoration of function of the heart or in its efficient support, performed by a physician in the duration of at least 30 minutes; resuscitation is done through artificial breathing and heart massage performed simultaneously.
- (5) Brain death is certified when
 - (a) a patient is in a condition on the basis of which the brain death diagnosis can be assumed and
 - (b) clinical manifestations of the brain death of a patient can be established enabling brain death diagnosis be certified on the basis of them, followed by an examination certifying irreversibility of the brain death.
- (6) Condition on the basis of which the brain death diagnosis can be assumed, clinical manifestations of the brain death of a patient enabling brain death diagnosis certification, examination certifying them, and examination certifying irreversibility of the brain death are stipulated in Appendix No. 2.
- (7) The Ministry shall state professional qualifications of the physicians certifying death and the physicians performing examination certifying irreversibility of brain death in a Regulation. The Ministry can state details of methods of examinations certifying death, of examinations certifying irreversibility of cardiac arrest or of brain death, as well as conditions for their performance, in a Regulation.

Article 11
Inadmissibility of removal from a deceased donor

- (1) A removal from a deceased donor shall be prohibited if
 - a) the deceased person in his/her lifetime or the legal representative of the deceased who was a minor or a legally incompetent person objected demonstrably to post-mortem removal of tissues organs (Article 16),
 - b) on the basis of evaluation of health capability it is not possible to rule out that the deceased suffered from a disease or a condition that might endanger the health or life of the recipient; evaluation of the health capability of deceased donor of organs shall be the responsibility of the health care facility performing the removal; in the event of donation of tissue the procedures of assessment of health capability of a deceased donor are governed by the Tissue and Cells Act, or
 - c) it is impossible to identify the deceased.
- (2) The evaluating physician shall make records on the evaluation of health capability of the deceased donor stating the scope of evaluation and the final decision regarding capability or incapability of the deceased donor for removal. This record bearing a dated signature of the evaluating physician shall be an integral part of medical records of the deceased donor.
- (3) Detailed terms and conditions of the evaluation of health capability and scope of examination of the deceased donor shall be specified by a Regulation of the Ministry.
- (4) Removal from a deceased foreign national may only be performed under the conditions stipulated by in an international agreement that is binding for the Czech Republic.

Article 12
Removed tissues and organs

- (1) Having performed the removal of tissue or an organ the physician shall record the list of removed tissues and organs as well as intended purpose of their use in medical records of the donor.
- (2) A postmortem examination of the deceased from whom the removal has been performed shall be carried out in such a time so that a decision on health incapability of the deceased can be taken in the event of a subsequent detection that the deceased suffered from a disease or a condition which could endanger the health or life of the recipient.
- (3) Removed tissues may be delivered for further examination, processing, preparation (conservation), storing and distribution only to a tissue bank.

Article 13
Post mortem examinations

- (1) The body of the deceased from whom a removal has been performed shall always be subject to a post mortem examination in accordance with a special legislation.
- (2) In the event that the physician examining the deceased person has a suspicion that death occurred under doubtful circumstances or as a result of an act of violence, including suicide or homicide, the removal may only be performed on the condition that the purpose of the post mortem examination ordered in accordance with a special legislation shall not be hampered. At the same time, it is necessary to inspect the removed tissue or organ, as well as the parts of the body from which these have been removed for further investigation so that the result of such an inspection may become part of the post-mortem certificate.

Article 14
Respect for the human body

During organ and tissue removal and during post mortem examinations the human body must be treated with respect and all procedures shall be carried out in such a manner that the body can be restored to its original appearance as far as this is possible.

Section 3

**Information on anticipated removal
given to the person with a close personal relationship
and objecting to post mortem removal**

Article 15

- (1) The treating physician of the patient from whom tissues or organs according to this Act can be supposed to be removed shall, in an appropriate manner, notify the persons having a close personal relationship with the donor, if the donor has not directed otherwise according to Article 19, (hereinafter only as the “appointed person”), of a presumed possibility of removal, provided that the appointed person expresses interest in the patient and that the patient, during his/her lifetime, has not in a demonstrable manner expressed a bid to share information on his/her health condition. In the event that the patient referred to in the first sentence is a minor or a legally incompetent person the treating physician shall notify the legal representative of a possibility of removal and, at the same time, shall instruct him/her about a possibility to express a demonstrable disapproval with a removal according to Article 16, Paragraph 1, Letter c). In this case the condition of expressed interest in the patient does not apply. At the same time, the treating physician shall explain the extent and purpose of the removal presumed to the appointed persons or to the legal representative, as the case may be, and this shall be done with due respect to the anonymity of the recipient. The appointed persons or the legal representative, as the case may be, have the right to raise questions, except questions relating to the recipient. In the event that the appointed persons or the legal

representative, as the case may be, reject information according to the fourth sentence, the physician shall respect their rejection and shall record this fact in the medical records of the patient.

- (2) In the event that tissues or organs according to this Act can be supposed to be removed from a deceased, the information and, if the deceased is a minor or a legally incompetent person, also the instruction according to Paragraph 1 shall be provided by a physician authorized by the statutory body of a health care facility the deceased person occurs at.
- (3) The information provided in accordance with Paragraph 1 shall be recorded by the physician in medical records of the patient or the deceased.

Article 16

- (1) Removal from the body of a deceased person can only be performed if the deceased during his/her lifetime, or a legal representative of a minor, or a legal representative of a legally incompetent person have not demonstrably expressed his/her disapproval. A disapproval shall be demonstrably expressed if
 - a) the deceased person has been registered with the National Registry of Persons Disapproving to Post-mortem Removal of Tissues and Organs, or
 - b) the deceased during his/her lifetime declares in front of his/her treating physician and one witness directly in a health care facility that he/she disapproves to a removal in the event of his/her death, or
 - c) a legal representative of a minor, or a legal representative of a legally incompetent person declares in front of a treating physician and one witness directly in a health care facility that he/she disapproves to a removal; in the event of a death of a minor or a legally incompetent person, such a declaration may be made during the lifetime, or after the death of this person.
- (2) A disapproval to the removal in accordance with Paragraph 1, Letter b) or c) shall be immediately recorded and the record shall be a part of medical records. This record shall be signed by the patient, the treating physician and the witness, and should the patient not be capable to sign with regards to his/her health condition, then the act of his/her will shall be confirmed by another witness. In the event of a minor or a legally incompetent person the record shall be signed by his/her legal representative and treating physician or, as the case may be, a physician referred to in Article 15, Paragraph 2. The record shall also state the date and hour when it was made. A health care facility shall send a copy of a record taken according to Paragraph 1, Letter b), or a copy of a declaration made for the event of death according to Paragraph 1, Letter c) to the National Registry of Persons Disapproving to post-mortem Removal of Tissues and Organs within 3 days of its draw-up.
- (3) In the event of not being established that a deceased has during his/her lifetime demonstrably expressed a disapproval to post-mortem removal the person is considered to have consented to a removal.

CHAPTER III

RECIPIENT

Article 17

- (1) The selection of most suitable recipients of organs is based on the principle of medical emergency and equity of recipients; should the medical emergency be equal, also the time for which the patient has been on the National Transplant Waiting List shall be taken into account.
- (2) The provisions of paragraph 1 shall not apply to removal of organs from living donors.
- (3) The recipient or his/her legal representative shall give his/her informed written consent to the transplantation, expressed on the basis of complete instruction given to the recipient by the physician assessing his/her health capability and/or by the physician performing transplantation to the recipient; in the event of providing complete instruction and giving informed written consent the provisions of Article 7 shall apply correspondingly. If due to the health condition of a recipient it is not possible to obtain his/her written consent or the consent of his/her legal representative, and if the transplantation is an urgent procedure saving the life or health of the recipient such a consent is assumed. Reasons for not obtaining patient's consent in accordance with the previous sentences shall be recorded in medical records of the recipient.
- (4) Information on health condition of a donor relating to the removal shall be a part of medical records of the recipient, too. Medical records containing information on health condition of the donor shall be kept in such manner as to provide for the anonymity of the donor.

CHAPTER IV

NATIONAL HEALTH REGISTRIES RELATED TO TRANSPLANTATIONS

Article 18

- (1) The National Registry of Persons Disapproving to Post-mortem Tissues and Organ Removal, National Registry of Organ Donors, National Registry of Persons Waiting for Organ Transplantation, National Registry of Performed Organ Transplantations as well as other Registries designed for recording of data related to organ donorship, as the case may be. These Registries shall be established by the Ministry in accordance with a special legal regulation.
- (2) If not stipulated otherwise by this Act administration of the Registries, collection of data in these as well as handling the data shall be governed by a special legal regulation.
- (3) Tasks in connection with the operation of the National Registry of Organ Donors, National Registry of Persons Waiting for Organ Transplantation, and the National Registry of

Performed Organ Transplantations shall be carried out by the Transplantation Coordination Center (Article 25) which is the administrator of personal data registered in these Registries on the basis of a special legal regulation. Tasks in connection with the operation of the National Registry of the Persons Disapproving to Post-mortem Removal of Tissues and Organ shall be carried out by the Coordination Center for Departmental Health Care Information Systems. For the purposes of management of the Registries, the Center referred to in the second sentence shall be the administrator of personal data in accordance with a special legal regulation.

- (4) The name, surname, birth registration number and the address of a person objecting to post-mortem tissue and organ removal, as well as all necessary data on the scope of the objection shall be entered into the National Registry of Persons Disapproving to Post-mortem Removal of Tissues and Organs. Necessary identification data of the donor, the person waiting for an organ transplantation, the person who has undergone a transplantation, as well as necessary data on health condition of these persons shall be entered in the National Registry of Organ Donors and the National Registry of Persons Waiting for Organ Transplantation. Details on the scope and the contents of data obligatorily entered into the National Registry of Persons Disapproving to Post-mortem Tissues and Organ Removal, the National Registry of Organ Donors, the National Registry of Persons Waiting for Organ Transplantation and the National Registry of Performed Organ Transplantations, as well as the set of data transferred from these Registries to the National Health Care Information System shall be stipulated by a Regulation of the Ministry. The Ministry may also stipulate in a Regulation a set of data transferred by the Center for Detection of Donors of Stem Cells from the registry of potential donors of stem cells into the National Health Care Information System.

CHAPTER V

OBLIGATIONS OF HEALTH CARE FACILITIES IN THE COURSE OF PROVIDING HEALTH CARE IN CONNECTION WITH DONATION AND TRANSPLANTATIONS OF TISSUES AND ORGANS

Article 19

Providing information on health condition of donor and recipient

- (1) Upon accepting a patient for treatment a health care facility shall require his/her written statement specifying which persons may be informed on his/her health condition. In the event that a patient is not able to make such a statement due to his/her health condition only persons with close relationship to the patient may be informed. Instead of minors or legally incapable persons the statement according to the first sentence shall be made by their legal representatives. Written statement is a part of medical records of a patient.
- (2) The right to obtain information on health condition of a minor have both parents, unless they have been relieved of parental responsibility, or other legal representatives of this person, foster parents and persons who care for the minors with their approval. In the event that

children and juveniles have been, on the basis of a request raised by a legal representative, a foster parent, or a court decision, placed with a nursery home, children's center for children up to 3 years of age, or with an educational detention establishment, statutory representatives of such establishments or employees authorized by them have also the right to obtain information according to the first sentence. In the event of a legally incompetent person his/her legal representative and persons who care for the legally incompetent person with the consent of the legal representative have the right to obtain information on health condition.

Article 20

Respecting anonymity between donors and recipients, information obligation of health care facilities

- (1) Health care facilities are obligated to respect anonymity of
 - a) a deceased donor of tissues or organs towards recipient,
 - b) a living donor of tissues or organs towards a person stipulated in Article 3, Paragraph 2 if the donor requires so
 - c) a living donor of a regenerative tissue unless he/she is not a person stipulated in in Article 3, Paragraph 2
- (2) Health care facilities are obligated to inform immediately the nearest transplant center (Article 22) on possible organ donors.

Article 21

Health care facilities performing removals and transplantations

- (1) The health care facilities other than transplantation centers (Article 22) shall perform tissue removals and transplantations in the scope given in the decision on authorization of a health care facility issued under a special legal regulation. In addition to obligations arising out of a special legal regulation, these health care facilities shall particularly
 - a) report persons who organs have been removed from to the national Registry of Donors,
 - b) report performed organ transplantations to the National Registry of Performed Organ Transplantations,
 - c) provide data required by the Transplantations Coordinating Center regarding tissues; the data provided shall be anonymized in such a way that both donor as well as the recipient of tissues cannot be identified,
 - d) detect information from the National Registry of the Persons Disapproving to Post-mortem Removal of Tissues and Organs for the purposes of performing removals from deceased donors, respect an objection to the removal expressed in this way,
 - e) verify other ways of demonstrable statement of objection to post-mortem organ and tissue removal stipulated by this Act and respect an objection expressed ion this way,
 - f) keep records on performed removals and transplantations and enter handling with removed organs into the protocol on final purpose of removed organs,

- g) provide for a long-term follow-up of living donors and recipients,
 - h) conclude a liability insurance policy, to the benefit of a donor for the case of an injury to his/her health that might be inflicted in connection with a removal, with an insurance company that has been granted permission to carry on insurance business in accordance with a special legal regulation. The scope of the insurance policy has to reflect potential risks connected with the removal,
 - i) have an import/export permit (Articles 26a thru 26g) to import or export organs.
- (2) Health care professionals taking part in a removal or a transplantation of organs shall enter the handling with a removed organ into the protocol which is attached to the organ removed. This protocol shall bear particularly the date and place of removal as well as final purpose of an organ removed. In the event that the organ removed is used for transplantation, the date, the place and the person whom the transplantation has been performed on shall be entered in the protocol. Should a decision that the organs removed are unsuitable be taken, the reason they have been found unsuitable for as well as the way of further handling with them shall be entered in the protocol. The protocol shall be sent to the Transplantations Coordinating Center within 7 days of taking a decision on final purpose of an organ.

Article 22

Transplant center

- (1) Transplant centers can be established only with a permission of the Ministry as a part of a hospital. Transplantation centers shall perform removals and transplantations of hematopoietic cells and organs in the scope given in the decision on the authorization of a health care facility issued under a special legal regulation.
- (2) Transplant centers performing transplantations of organs shall fulfill obligations according to Article 21 and apart from that they shall
- a) report persons indicated for organ transplantation to the National Registry of Persons Waiting for Organ Transplantation,
 - b) transplant organs solely to recipients registered in the National Registry of Persons Waiting for Organ Transplantation,
 - c) Cooperate with the Transplantation Coordination Center when appointing the most suitable organ recipients,
 - d) having obtained information in accordance with Article 20, paragraph 2, verify whether all conditions regarding a removal have been fulfilled (Articles 10 and 11),
 - e) inform the Transplantation Coordination Center about the potential donor, having detected that conditions for a removal have been met.
- (3) Transplant centers performing transplantations of hematopoietic cells shall fulfill obligations according to Article 21, Paragraph 1, Letters c), g) and h) and, apart from that, they shall cooperate with centers for search for donors of hematopoietic cells (Article 24) when choosing the most suitable non-related potential donors of hematopoietic cells.

Article 21
Tissue bank

- (1) Tissue bank is designated for removal, further processing, examination, preservation, storing and distribution of tissues intended for transplantations; performing its activities in accordance with the Human Tissue and Cells Act.
- (2) Tissue banks shall
 - a) cooperate with departments of pathology, forensic medicine, gynecological-obstetric departments of health care facilities, with blood transfusion facilities and with the health care facilities referred to in Articles 21 and 22,
 - b) use information provided by the National Registry of Persons Disapproving to Post-mortem Tissues and Organs and the National Registry of Organ Donors,
 - c) keep records on removed and received tissues, performed screening and testing of removed tissues, on prepared transplantable tissue grafts being stored and the grafts delivered to the facilities performing transplantations.

Article 24
Center for Search for Donors of Hematopoietic Cells

- (1) Center for Search for Donors of Hematopoietic Cells is intended for the searching for non-related donors of hematopoietic cells, their examination and mediating transplantations of hematopoietic cells donated by non-related donors. Center for Search for Donors of Hematopoietic Cells may be established only with the approval of the Ministry.
- (2) The Center for Search for the Donors of Hematopoietic Cells shall particularly
 - a) keep records on performed examinations of potential donors of hematopoietic cells and on mediation of transplantation of hematopoietic cells,
 - b) maintain a registry of potential donors of hematopoietic cells,
 - c) provide, on the basis of a request of a health care facility, information on potential donors of hematopoietic cells from the point of view of evaluation of their suitability for a specific recipient,
 - d) ensure and coordinate international cooperation in exchange of hematopoietic cells intended for transplantation.

Article 25
Transplantations Coordination Center

- (1) The Ministry shall establish the Transplantations Coordination Center to arrange and mediate transplantations. Establishing the Transplantations Coordinating Center the Ministry shall act so that the Transplantations Coordinating Center maintain its independence on transplant centers with regards to space, material and technical equipment and location of the seat of the Center. An employee of a hospital a part of which is a transplant center must not be in labor

relation with the Transplantations Coordinating Center on the basis of a labor contract or on any other similar basis.

- (2) The Transplantations Coordination Center shall fulfill the following tasks. It shall
- a) maintain the National Registry of Persons Waiting for Organ Transplantation,
 - b) maintain the National Registry of Organ Donors,
 - c) maintain the National Registry of Performed Organ Transplantations,
 - d) coordinate removal and transplant teams of individual transplant centers,
 - e) appoint the most suitable recipients for removed organs; selection is performed only from the National Registry of Persons Waiting for Organ Transplantation,
 - f) process overall data on performed removals, transplantations and their results for the previous year and prepare a report that shall be submitted to the Ministry by March 31st of the following calendar year,
 - g) coordinate methodically activities of the center for search for donors of hematopoietic cells,
 - h) ensure and coordinate international cooperation in exchange of organs intended for transplantation (Article 26),
 - i) Fulfill other tasks assigned by the Ministry.

CHAPTER VI

INTERNATIONAL COOPERATION

Article 26

- (1) International exchange of organs and tissues is only allowed if its aim is to find the most suitable recipient or save a patient waiting for a transplantation whose life is imminently jeopardized, namely on the basis of membership in international transplantation organizations or on the basis of international treaties the Czech Republic is bound by.
- (2) An offer of an organ to a foreign country in terms of international exchange of organs under Paragraph 1 may only be made if there is no suitable patient waiting for transplantation registered in the Czech Republic in the National Registry of Persons Waiting for Organ Transplantation or if the offer is based on membership in international transplantation organizations.
- (3) An offer of an organ to a foreign country may also be made on the basis of a permission issued by the Ministry. The Ministry shall grant a permission if there is no suitable patient waiting for transplantation registered in the National Registry of Persons Waiting for Organ Transplantation and the offer of an organ to a foreign country cannot be made on the basis of membership in international transplantation organizations or on the basis of an international treaty the Czech Republic is bound by.
- (4) Organs for transplantations from abroad in terms of international exchange under Paragraph 1 may only be accepted in the event that the removal has been performed by a duly qualified

health care facility and in such a manner which is in harmony with effective legislation of the country of origin. It has to be verified that the health capability of the donor before the removal was examined prior to the removal, and medical records of the donor relating to the removal have to be traceable.

- (5) The terms and conditions concerning international cooperation in the field of hematopoietic cell transplantation may be stipulated by a Regulation of the Ministry.

Article 26a

- (1) The Ministry shall issue an import/export permit to import or export tissues or to import or export organs within the bounds of international exchange or of an offer according to Article 26, Paragraph 1 thru 3 (hereinafter only as “import or export of tissues or organs”). An application for an import or export permit is presented to the Ministry by the health care facility realizing such an import or export (hereinafter only as “the Applicant”) not later than 90 calendar days prior to beginning of intended import or export.
- (2) An application for granting an import or export permit shall contain
- a) identification data of the applicant,
 - b) a ten-digit sub-item of combined joint customs tariff and its name stating stipulated tissues or organs to be imported/exported which the import/export is applied for, according to a Governmental Order (Article 26e),
 - c) maximum amount of tissues or organs in pieces or cells in millilitres,
 - d) proposed time of effectiveness of the import/export permit,
 - e) the purpose of import/export,
 - f) the name of the country (countries) of origin of tissues or organs in the event of import, the name of the country (countries) of destination of tissues or organs in the event of export,
 - g) date of execution, full name of the person authorized to act in the name of the applicant, a signature of this person and a stamp-print of the applicant.
- (3) The following materials shall be attached by the applicant to the application for granting an import or export permit
- a) an extract from the Commercial Register, or a legally attested copy of the Memorandum of Association,
 - b) a list and specification of kinds of exported or imported tissues or organs,
 - c) in the event of export a document or a legally attested copy issued by a state authority certifying the health care facility is authorized to perform removals of tissues or organs.
- (4) In the event that an application does not contain all data stipulated in Paragraphs 2 and 3 the Ministry shall return it to the applicant setting an appropriate time to complete the application. The time provided for the completion of an application is not included in the time limit reserved for a decision on granting an import or export permit. In the event that the

applicant does not complete the application within the appointed time the Ministry shall discontinue the administrative action on issuing an import or export permit.

Article 26b

- (1) An application for granting an import or export permit shall contain
 - a) identification data of the applicant,
 - b) evidence number of the import or export permit,
 - c) the sub-item of combined joint customs tariff and its name stating tissues or organs import and exported of which is subject to the import or export permit,
 - d) validity deadline of the import or export permit including maximum permitted amount of tissues or organs in pieces or cells in millilitres which may be imported or exported,
 - e) the name of the country (countries) of origin of tissues or organs in the event of import or the name of the country (countries) of destination of tissues or organs in the event of export,
 - f) other terms and conditions, if necessary
 - g) a notice of obligation to return the import or export permit within 10 working days from its exhaustion or termination of its validity (Article 26e),
 - h) the purpose of import or export,
 - i) instruction of legal remedy,
 - j) appendices to the decision; each appendix contains a space reserved for entry of identification data of a health care facility which has performed the removal of tissue or of an organ as well as for entries of customs authorities on utilization of granted import or export permit (amount, date, stamp-print, signature); the number of appendices corresponds to the number of permitted maximum import or export according to Letter d),
 - k) date of issue, signature of an authorized employee of the Ministry and a stamp-print.
- (2) The Ministry shall issue an import or export permit for a period of time not longer than 12 months.

Article 26c

- (1) The Ministry shall not issue an import or export permit in the event that
 - a) all conditions stipulated in Article 26a, Paragraphs 2 and 3, are not met, or
 - b) it is required by interests of security of the Czech Republic (possible risk of endangering health and life of population).
- (2) The Ministry shall withdraw an import or export permit in the event that
 - a) the import or export permit has been issued on the basis of false or incomplete data,
 - b) the terms and conditions, or the scope given in the permit were not met, or
 - c) it is required by interests of security of the Czech Republic.

- (3) An appeal against a decision on withdrawal of an import or export permit according to Paragraph 2 does not have suspensive effect.
- (4) Any and all written petition shall be in Czech language and documentary evidence shall be furnished with an official translation into Czech language.
- (5) The Ministry and the General Directorate of Customs mutually exchange data regarding to import or export permits, namely at the extent of data stipulated in the decision according to Paragraph 26b. They inform each other about facts significant for administrative proceedings on issuing, non-issuing and/or withdrawing an import or export permit according to this Act, control meeting conditions given in import or export permits and sanctions imposed.

Article 26d

Actions of the Ministry in the course of the issuing and withdrawing of import or export permits shall be pertinent to the Administrative Code, if not stipulated otherwise in this Act.

Article 26e

An import or export permit cannot be assigned to, nor does it pass on, a legal successor. A health care facility which an import or export permit has been issued to is obligated to return such a permit to the Ministry within 10 working days upon its exhaustion or termination of validity, including related records of customs authorities on its utilization as well as a list of state authority approved health care facilities in foreign countries which organs or tissues has been exported to, or imported to the Czech Republic from.

Article 26f

The Government shall issue an Order for implementation of Article 26a, Paragraph 2, Letter b).

Article 26g

For imports or exports of tissues or organs between the Czech Republic and member states of the European Union the provisions of Articles 26a thru 26d shall be applied accordingly.

CHAPTER VII
OTHER ACTIVITIES
RELATED TO DONATION, REMOVAL AND TRANSPLANTATIONS

Article 27
Information for the public

The Ministry shall ensure that information on the importance and the possibilities of donation of tissues and organs, especially donation of hematopoietic cells, on the way of expressing disapproval to post-mortem removal, and on the importance of teransplantations. Pursuing this, the Ministry shall cooperate with other administrative bodies, municipalities, health insurance companies, health care facilities, professional health care organizations and other bodies and institutions.

Article 28
Prohibition of financial gain or other inducements
and prohibition of organ and tissue trafficking

- (1) Human body and its parts shall not give rise to financial gain or comparable advantage.
- (2) Donor and other person shall not rise any claims towards the recipient.
- (3) Advertising and promotion for the purpose of demand or offer of organs are prohibited. Activities performed according to Article 27 shall not be considered advertising and promotion.
- (4) Commercial trade in tissues and organs for the purpose of transplantation shall be prohibited.

CHAPTER VIII
SANCTIONS

Article 29

- (1) A fine may be imposed for a failure or breach to fulfill the obligations and/or bans stipulated by this Act (hereinafter only as “unlawful conduct”). A fine on a health care facility shall be imposed by the administrative body that has issued permit to the facility in accordance with a special legal regulation. A fine on legal entities and individuals who carry on business activities on their own behalf and are not a health care facility shall be imposed by a municipality on the territory of which the legal entity has its seat, or an individual carrying on business activities on his/her own behalf has his/her permanent residence.

- (2) A fine can be imposed on
- a) a health care facility
 - 1) up to the amount of 100,000.00 CZK for a failure or breach to fulfill the obligations stipulated in Article 3, Article 4, Article 6 Paragraph 1, Article 8 Paragraph 1, Articles 10 thru 13, Article 16 Paragraphs 1 and 2, Article 20 Paragraph 1, Article 21, Article 22 Paragraphs 2 and 3, Article 23 Paragraph 2, Article 24 Paragraph 2, Article 25 Paragraph 2, Article 26 Paragraphs 1 thru 3 and Article 28 Paragraph 3;
 - 2) up to the amount of 50,000.00 CZK for a failure or breach to fulfill the obligations stipulated in Article 6 Paragraph 3, Article 7 Paragraphs 1 thru 3 and Paragraph 6, Article 8 Paragraph 2, Article 9 Paragraph 1, Article 12 Paragraph 1, Article 16 Paragraph 3 and Article 19;
 - 3) which imports or exports organs without an import or export permit up to the amount of 5,000,000.00 CZK,
 - 4) which imports or exports organs in contrary to an issued import or export permit up to the amount of 1,000,000.00 CZK,
 - b) legal entities and individuals who carry on business activities on their own behalf up to the amount of 500,000.00 CZK for a breach of the prohibition stipulated by Article 28, Paragraph 3.
- (3) Unlawful conduct referred to in Paragraph 2 shall be considered a repeated violation if a health care facility, a legal entity or an individual who carries on business activities on his/her own behalf violated the Act within one year from a previous violation for which a lawful fine has been imposed in accordance with paragraph 2.
- (4) For repeated unlawful conduct the maximum fines indicated in Paragraph 2 shall be increased by one half.

Article 30

- (1) The administrative body that has imposed a fine on a health care facility shall deliver a copy of the decision on the fine imposed in accordance with this Act to the health insurance company with which the health care facility has concluded a contract on providing of health care.
- (2) A proceedings on the imposing of a fine may only be commenced within 1 year of the date when the administrative body authorized to impose the fine or the municipality authorized to impose the fine got aware of the unlawful conduct, but not later than within 3 years of the date when the violation was committed.

- (3) When imposing a fine and determining its amount, graveness of the violation shall be taken into account, as well as the consequences, the extent of the fault, and the circumstances under which the violation was committed.
- (4) The fine shall be collected and enforced by the administrative body that has imposed it or the municipality that has imposed it. The fine imposed by the Ministry shall be the income of the state budget, the fine imposed by the region shall be the income of the regional budget, the fine imposed by the municipality shall be the income of the community budget. To the collection and enforcement of fines a special legal regulation shall apply.
- (5) If the unlawful conduct referred to in Article 29, Paragraph 2 constitutes the subject of unlawful conduct in accordance with a different legal regulation and the relevant administrative body has commenced the proceedings on the imposing of the fine in accordance with a different legal regulation, the proceedings concerning the imposing of the fine in accordance with this Act shall be discontinued.

CHAPTER IX

COMMON AND TEMPORARY PROVISIONS

Article 31

When in this Act expressions “donor” and “donorship” are used no general legal rules and regulations governing donations and the facts connected with it shall apply.

Article 32

- (1) Health care facilities performing removals and transplantations, transplant centers, tissue banks, centers for search for donors of hematopoietic cells, and parts of national health registries (Article 18) shall meet the obligations stipulated by this Act not later than within 2 years of the entry of this Act into effect.
- (2) The Ministry shall inform the public on the establishment of the National Registry of the Persons Objecting to Post-mortem Organ or Tissue Removal and on the manner in which these person may register with the Registry in such a way so as to make the information as wide-spread as possible. Until the Registry is established, current legal rules and regulations shall apply to the cases when people object to post-mortem organ and tissue removal, with the exception of the cases when a person objected in accordance with Article 16, Paragraph 1, Letter b).

PART TWO
Amendment of the Penal Code

Article 33

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PART THREE
Amendment of the Act on Public Health Insurance System and on the Amendment and Modification of Some Related Acts

Article 34

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PART FOUR
Amendment of the Misdemeanors Act

Article 35

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PART FIVE
Amendment of the Health Care Act

Article 36

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PART SIX
Amendment of the Act on Health Care in Private Medical Facilities

Article 37

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PART SEVEN
Amendment of the Act on the Czech Chamber of Physicians, the Czech Chamber of Dentists, and the Czech Chamber of Pharmacists

Article 38

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PART EIGHT
Entry into effect

Article 39

This Act shall enter into effect on September 1, 2002, except Part Five, Points 3 and 5 which shall enter into effect on March 1, 2003.
