

## Act No. 576/2004 Coll.

of 22 September 2004

### On healthcare, healthcare-related services and on the amendment and supplementing of certain laws

THE NATIONAL COUNCIL OF THE SLOVAK REPUBLIC HAS  
RESOLVED ON THE FOLLOWING ACT:

#### *Article I*

### PART ONE

## BASIC PROVISIONS

### § 1

#### Subject of arrangement

This Act regulates the healthcare provision and healthcare-related services, the rights and obligations of natural persons and legal entities while providing healthcare, the procedure taken upon the death and the execution of State administration in the healthcare sector.

### § 2

#### Definition of basic concepts

(1) Healthcare is a set of professional activities performed by medical workers, including provision of medicaments, medical aids and dietetic foodstuffs in order to prolong life of a natural person (hereinafter “person”), improve the quality of his/her life and ensure the healthy development of future generations; healthcare includes prevention, dispensation, diagnostics, treatment, bio-medical research, nursing care and midwifery.

(2) Healthcare performance is an integral activity of a medical worker which constitutes the basic unit of the healthcare provision.

(3) Emergency healthcare (hereinafter “emergency

care”) is a healthcare provided to a person in case of a sudden change of the health condition directly endangering life, potentially seriously endangering his/her health if not provided fast, causing a sudden and intolerable pain or provoking sudden changes of behaviour and action under influence of which the person directly endangers themselves or surroundings. Emergency care is healthcare provided in the case of a birth as well. Emergency care includes emergency transportation of a person to a medical facility, emergency transportation from one medical facility to another and emergency transportation of donors of organs, tissues and cells for the purposes of transplantation performed by medical rescue services providers.<sup>1)</sup>

(4) Attending medical worker is a medical worker assigned by a healthcare provider (hereinafter “provider”) to provide healthcare to a person; if this attending medical worker is a doctor or a dentist, we speak about attending physician, if the attending medical worker is a nurse or a midwife, we speak about attending nurse or attending midwife. If the provider is a natural person, this person is attending medical worker.

(5) Board of consultants is an advisory body of the attending medical worker consisting of medical workers assigned by the provider, which are in relation to the provided healthcare attending medical workers.

(6) Medical record is a set of data on health condition of a person or healthcare and healthcare-related services provided to the person.

(7) For the purposes of this Act, a prevention is

- (a) education and training with the objective to assure protection, preservation or recovery of health of a person,
- (b) active search for eventual reasons of diseases, their removal and prevention of diseases,

- (c) search for pathological processes in their asymptomatic period with the objective of treatment that prevents their clinical symptoms,
- (d) active disease monitoring with the objective to prevent of the health deterioration of a person.

(8) Dispensation is an active and systematic monitoring of health condition of a person with health deterioration prognosis and examination and treatment of the person.

(9) Diagnostics is detection and assessment of health condition of a person. In case of identified health damage or a disease it is also the determination of its severity; it results in identification of disease.

(10) Treatment is a conscious affection of the health condition of a person for recovery of the health of a person, prevention of further deterioration of the health condition or mitigation of symptoms and consequences of the disease.

(11) Treatment regimen is a regimen of a person to support the treatment determined by the attending physician.

(12) Bio-medical research is an acquisition and verification of new biological, medical, nursing and midwifery knowledge carried out on human beings. Bio-medical research in the field of nursing and midwifery allows support of individuals' and families' capacities or improve the optimum of functions and minimise those causing diseases as well.

(13) Nursing care is a health care provided by a nurse with required professional qualification as per a separate regulation<sup>2)</sup> using the method of nursing process within the nursing practice.

(14) Nursing practice is a practical performance of nurse and midwife services while

- (a) providing nursing care and midwifery,
- (b) managing and providing outpatient healthcare (hereinafter "outpatient care") and inpatient healthcare (hereinafter "inpatient care") using the method of nursing process.

(15) Nursing practice includes especially

(a) evaluation of nursing care needs and sources to secure them,

b) maintaining the nursing documentation which is a part of the medical records, and evaluation of the nursing care results,

(c) patient education leading to support, preservation and recovery of his/her health, and providing information about necessary nursing care,

(d) medical workers education in the field of nursing care and professional ethics,

(e) cooperation with another medical and other specialised workers in the field of healthcare of a pertinent healthcare facility and cooperation with another natural persons and legal entities while planning, providing, coordinating and evaluating of the nursingcare.

(16) Midwifery is healthcare for a woman and child provided by a midwife with required professional qualification as per a separate regulation<sup>2)</sup> during physiological pregnancy, labour and lying-in, healthcare for reproductive health and provision of nursing care for gynaecological and obstetric diseases. Midwifery is provided using the method of nursing process within the midwifery practice.

(17) Midwifery practice is managing and providing the midwifery care using the method of nursing process. Midwifery practice includes especially:

(a) determination of the midwifery and nursing needs and the sources to secure them,

(b) maintaining the midwifery and nursing documentation which is a part of the medical records, and evaluation of the results of midwifery and nursing care,

(c) reproductive health care,

(d) education of medical workers in the field of midwifery and professional ethics,

(e) cooperation with another medical and other specialised workers in the field of healthcare of

a pertinent healthcare facility and cooperation with another natural persons and legal entities while planning, providing, coordinating and evaluating of the nursing care.

(18) Nursing process is a systemic, rational and individualised method of planning, providing and documenting of the nursing care and midwifery. Its objective is determination of the real or projected healthcare related problems of a person, planning the fulfilment of the detected needs, executing, documenting and evaluation of the specific nursing interventions necessary for their fulfilling. Establishing a nurse diagnosis is a part of the nursing process. A list of the nurse diagnoses shall be defined in a generally binding legal regulation issued by the Ministry of Health of the Slovak Republic (hereinafter “Ministry of Health”).

(19) Medical emergency service is a healthcare ensuring the permanent availability of a general outpatient care and outpatient care in the specialised field of dentistry.

(20) Institutional emergency service is a healthcare ensuring the permanent availability of an inpatient care in hospital.

### § 3

#### Catalogue of Medical performances

(1) Catalogue of Medical performances is a summary of medical performances, their frequencies and indication restrictions related to individual diseases as per Annex 1, which constitute an essential requisite for the correct healthcare provision (§ 4 subsection 3), with the exception of medical performances fully covered by public health insurance as per a separate regulation.<sup>3)</sup>

(2) The Ministry of Health shall constitute the Cataloguing Commission for Medical performances as an advisory body for professional evaluation of medical performances corresponding to diseases as per Annex 1.

(3) The Catalogue of Medical performances shall include those medical performances leading by a specific disease to

(a) saving of life,

(b) curing of disease,

(c) prevention of the onset of serious health complications,

(d) prevention of a deterioration in the severity of a disease or its transition to a chronic state,

(e) effective prevention,

(f) early ascertainment of disease,

(g) mitigation of the symptoms of disease.

(4) The Catalogue of Medical performances shall also include medical performances necessary for providing healthcare in specific cases (§ 26 to 40).

(5) Criteria for incorporating of medical performances into the Catalogue of Medical performances are:

(a) effectiveness of a medical performance in the field of prevention, diagnostics or treatment of a specific disease,

(b) benefit of a medical performance in the field of prevention, diagnostics or treatment of a specific disease in reducing morbidity and mortality,

(c) improvement of prevention, diagnostics or treatment of a specific disease in comparison with the existing possibilities of prevention, diagnostics or treatment.

(6) Medical performances shall be discarded from the Catalogue of Medical performances upon the proof that in terms of prevention, diagnostics or treatment of a specific disease

(a) those medical performances do not meet satisfying results or

(b) there are more effective medical performances included in the Catalogue of Medical performances.

(7) Cataloguing Commission for Medical

performance consists of eleven members, three of them nominated by the Ministry of Health, another three nominated by the health insurance companies and five nominated by the professional companies.

(8) The activities of the Cataloguing Commission for Medical performances shall be governed by a regulation issued by the Ministry of Health.

(9) The Catalogue of Medical performances shall be issued by the Government of the Slovak Republic by decree.

## PART TWO

### PROVISION OF HEALTHCARE AND HEALTHCARE-RELATED SERVICES

#### § 4

##### Initial provisions

(1) Healthcare and healthcare-related services shall be provided by a provider and medical workers under conditions laid down by a separate regulation.<sup>4)</sup>

(2) Healthcare shall be provided in relation to the disease determined by a medical worker.

(3) Healthcare is provided correctly if all medical performances necessary for determination of the disease are executed without undue delay and a correct preventing or treatment procedure is provided.

(4) An informed approval shall be required for healthcare provision (§ 6 subsection 4), unless stipulated otherwise herein (§ 6 subsection 8).

(5) Maintaining of medical records is an integral part of healthcare provision (§ 2 subsection 6).

#### § 5

##### Reviewing of ethical issues in healthcare provision

(1) Ethical issues arisen in healthcare provision and ethical acceptability of bio-medical research projects (§ 2 subsection 12) shall be reviewed by an independent Ethical commission (hereinafter “Ethical commission”).

(2) Ethical commission shall be established by

(a) the Ministry of Health to review the ethical issues arisen in healthcare provision including bio-medical research,

(b) a self-governing region to examine the ethical acceptability of bio-medical research projects and the ethical issues arisen in outpatient care provision,

(c) an inpatient care provider to examine the ethical acceptability of bio-medical research projects and the ethical issues arisen in inpatient care provision.

(3) Ethical commission consists of five members at least; it is composed of medical workers, other specialized workers whose specialisation is required for the Ethical commission activities, and persons without competency in healthcare or research. Each Ethical commission also includes a representative nominated by professional healthcare organisations. The number of Ethical commission members without competency in healthcare or research may not exceed a majority of more than a half of all members of the Ethical commission.

(4) Members of Ethical commission are obliged to

(a) notify the founder of the Ethical commission on the facts that constitute or could constitute a conflict of interests in the case of a specific reviewed project; if a member of the Ethical commission fouls into conflict of interests, he/she may not participate in reviewing and making standpoint of the Ethical commission for such a project,

(b) uphold confidentiality on all circumstances learnt upon performance of their posts; the obligation to uphold confidentiality does not refer to cases where those circumstances are unveiled with the consent of the concerned person.

(5) The Ethical commission is obliged to keep records on its activities, records from meetings, conclusions, standpoints and recommendations. The founder of a pertinent Ethical commission is obliged to ensure their archiving within the period of 20 years.

(6) The Ethical commission issues its standpoints in writing; in each standpoint it must justify its conclusions. In order to adopt a standpoint of the Ethical commission a majority of two thirds of all commission members is required.

(7) Activities of an Ethical commission shall be governed by a decree issued by the founder of the pertinent Ethical commission.

## § 6

### Instructing and informed approval

(1) The attending medical worker is obliged to notify on purposes, nature, impacts and risks of healthcare provision, on options of proposed procedures, and on risks of rejecting healthcare (hereinafter “to instruct”)

(a) a person whom the healthcare is to be provided or another determined person,

(b) a legal representative, tutor or a foster of an under-aged child<sup>5)</sup> (hereinafter „legal representative“), if the person whom healthcare is to be provided is a child, person deprived of the capacity to execute legal acts or person with the restricted capacity to execute legal acts (hereinafter „person unapt to give an informed approval“), and also a person unapt to give an informed approval in an appropriate way.

(2) The attending medical worker is obliged to give a comprehensible, understanding instruction without restraint, with a possibility and sufficient time to opt

freely for an informed approval, and in appropriate way to the intellectual, volitive and health condition of the instructed person.

(3) Whoever entitled to instruction as per subsection 1 shall also be entitled to reject the instruction. A written record on rejection of the instruction shall be made.

(4) An informed approval is a proven approval with healthcare provision preceded by instruction as per this Act. An informed approval shall also be a proven approval with healthcare provision preceded by a refusal of instruction, unless stipulated otherwise herein (§ 27 subsection 1, § 36 subsection 2, § 38 subsection 1, § 40 subsection 2).

(5) Informed approval shall be given by

(a) a person whom the healthcare is to be provided or

(b) a legal representative, if the person whom the healthcare is to be provided is unapt to give an informed approval; such a person shall participate in decision making to the highest possible extent allowed by his/her abilities.

(6) If the legal representative rejects to give an informed approval, the provider can submit an application to a pertinent court, if this is in the interest of the person unapt to give an informed approval whom the healthcare is to be provided. In this case the informed approval of the legal representative is substituted by a court approval with the healthcare provision. Only those medical performances necessary to save life of this person shall be allowed until the court rules.

(7) Whoever entitled to give an informed approval shall also be entitled to abjure it freely anytime.

(8) An informed approval shall not be required in case of

(a) emergency care, if the informed approval is not possible to gain on time, but it is presumable,

(b) a protective treatment ordered by a court as

per a separate regulation,<sup>6)</sup>

- (c) an inpatient care, if the concerned person
  1. communicates an infective disease seriously endangering his/her surrounding or
  2. endangers oneself or his/her surrounding due to a mental illness or with symptoms of a mental defect, or there is a risk of a serious deterioration of health condition of the person.

(9) Instructive method, content of instruction, rejection of instruction, informed approval, rejection of informed approval and abjuration of informed approval shall be recorded in the medical records (§ 21). If the informed approval was given by the legal representative [subsection 5 point b)], a statement of the person unapt to give an informed approval with health-care provision shall also be recorded in medical records.

### § 7

#### Forms of healthcare provision

- (1) Healthcare is provided as
  - (a) outpatient care
    1. general,
    2. specialised,
  - (b) inpatient care,
  - (c) pharmaceutical care.
- (2) Medical emergency services shall be provided within general outpatient care at least to the scope of the public minimum network of providers.<sup>7)</sup>
- (3) Institutional emergency services shall be provided within inpatient care in hospital at least to the scope of the public minimum network of providers.

### § 8

#### Outpatient care

(1) Outpatient care is provided to a person whose health condition does not require the permanent healthcare provision for more than 24 hours. Outpatient

care is also provided at home or in another natural environment of the person whom the healthcare is to be provided (hereinafter “home care”).

(2) General outpatient care is provided by a doctor with specialisation in the specialised field of general medicine and a doctor with specialisation in the specialised field of paediatrics (hereinafter “a general practitioner”) assigned by the provider and a nurse with pertinent professional qualification assigned by the provider.

(3) Specialised outpatient care is provided by a doctor with specialisation other than general medicine assigned by the provider, a dentist (hereinafter „a specialist physician“) or a medical worker<sup>8)</sup> with pertinent professional qualification.

(4) Home care provided by a nurse or a midwife with pertinent professional qualification using the method of nursing process is home nursing care.

### § 9

#### Inpatient care

- (1) Inpatient care is provided upon
  - (a) recommendation of the attending physician, if the health condition of a person requires a permanent healthcare provision for more than 24 hours or
  - (b) court ruling.
- (2) Recommendation of the attending physician to take person to inpatient care shall include reasons of taking the person to inpatient care and an excerpt from medical records [§ 24 subsection 1].
- (3) The health service body of the Prison and Judicial Guard shall decide on taking arrested or imprisoned person to inpatient care. It shall also ensure the necessary protection of the person and the provider.
- (4) In case of inpatient care with no informed approval required as per § 6 subsection 8 part c), the provider is obliged to notify a court covering the territory of the inpatient health care facility by 24 hours

on taking the person to inpatient care. The court shall rule on legitimacy of reasons for taking the person to inpatient care. Only those medical performances necessary to save the life and health of the person or to protect his/her surrounding are allowed until the court rules.

(5) If the grounds for taking person to inpatient care with no informed approval required elapse, the provider is obliged to release the person from inpatient care or to require the informed approval (§ 6 subsection 4 and 5).

(6) The provider shall release person from inpatient care

(a) if the grounds for inpatient care elapse,

(b) upon moving to another inpatient care provider or

(c) upon his/her request or request of his/her legal representative, if despite an appropriate instruction he/she rejects inpatient care, if this is not the case of court-ordered inpatient care or inpatient care on the legitimacy of which the court rules.

(7) In the case of releasing a person unapt to give an informed approval from inpatient care the attending physician is obliged to notify on this his/her legal representative in advance.

(8) When releasing a person from inpatient care, the attending physician shall

(a) instruct the person or his/her legal representative on the treatment regimen and the further treatment procedure,

(b) provide the person with the necessary medications for three days following the release from inpatient care and record this fact to the release report,

(c) elaborate the therapeutic release report by the day of release from inpatient care and send it to the pertinent general practitioner without undue delay and

1. to another attending physician, if the person was taken to inpatient care upon his/her recommendation or

2. to another inpatient care provider, if the person is moved to another inpatient care provider,

(d) file a copy of the therapeutic release report to medical records.

(9) When releasing a person from inpatient care, the attending nurse or attending midwife shall

(a) instruct the person or his/her legal representative on the nursing care and the further nursing process,

(b) elaborate the nursing release report containing evaluation of the nursing process by the day of release from inpatient care and send it to the pertinent general practitioner and another nursing care provider in case of continuation of nursing care, and submit a copy of it to the person or his/her legal representative,

(c) file a copy of the nursing release report to medical records.

(10) Therapeutic release report is an excerpt from medical records (§ 24 subsection 1) maintained by the attending physician when providing inpatient care. Nursing release report is an excerpt from medical records (§ 24 subsection 1) maintained by the attending nurse or attending midwife when providing inpatient care.

## § 10

### Pharmaceutical care

Pharmaceutical care is governed by a separate regulation.<sup>9)</sup>

## § 11

### Rights and obligations of persons in the process of healthcare provision

(1) Each person is entitled to the healthcare provision.

(2) The right for the healthcare provision is guaranteed equally to everybody in accordance with the principle of the equal treatment in healthcare set out by a separate regulation.<sup>10)</sup> In line with the principle of equal treatment, the following is forbidden: discrimination due to gender, religion or faith, marital and family status, colour of skin, language, political and other opinions, activities in the trade unions, national or social origin, health disability, age, property, family line or another status.

(3) The execution of rights and obligations resulting from this Act must be in accordance with good manners. No one may abuse these rights and obligations to harm another person. The person may not be persecuted nor punished in any other way in connection with carrying out his/her rights for lodging a complaint, accusation or a proposal for commencement of prosecution against another person, medical worker or provider.

(4) Whoever believes his/her rights or legally protected interests were infringed in consequence of failure to equal treatment is entitled to seek court protection as per a separate Act.<sup>11)</sup>

(5) The provider may not persecute nor disadvantage the person inasmuch as the person claims his/her entitlements in accordance with this Act.

(6) Each person is entitled to choose his/her own provider. This entitlement shall not apply to

- (a) an arrested or imprisoned person,
- (b) an asylum seeker.<sup>12)</sup>

(7) The entitlement to choose a provider shall not apply to a person who is

- (a) a member of Armed Force of the Slovak Republic,
- (b) a member of the Police Force,
- (c) a member of the Slovak Information Service,
- (d) a member of the National Security Office,

(e) a member of the Prison and Judicial Guard Corps,

(f) a member of the Railway Police,

(g) a member of the Fire and Emergency brigade, if the provider was determined by the service body or service authority.

(8) Subject to the conditions stated herein each person is entitled to

(a) protection of one's dignity, physical and mental integrity,

(b) be informed on one's health condition,

(c) be informed on the purposes, nature, impacts and risks of healthcare provision, on the options of proposed procedures, and on the risks of rejecting healthcare (§ 6 subsection 1),

(d) reject healthcare with the exception of cases when subject to the conditions stated herein the healthcare may be provided even without the informed approval (§ 6 subsection 8),

(e) decide whether or not to take part in education or bio-medical research,

(f) reject the removal and transfer of organs, tissue or cells after the death,

(g) upholding confidentiality on all information regarding one's health condition, all circumstances related to one's health condition, unless in cases stipulated by a separate regulation<sup>13)</sup>, the medical worker is deprived of this obligation,

(h) palliative care,

(i) humane, ethical and dignified approach of medical workers.

(9) Under conditions laid down by a separate regulation<sup>14)</sup> each person is entitled to refuse an autopsy.

(10) A woman who has made a written request for nondisclosure of her identity in connection with the

delivery is entitled to special protection of her personal data.

(11) Each person is obliged to provide or mediate necessary help to anyone in danger of death or anyone showing severe health damage unless one's health is not severely endangered by such help.

(12) A person with infectious disease is obliged

(a) to prevent communication of such disease to other persons,

(b) to indicate the source of infection, if known, to the attending physician, and provide all information on its detection,

(c) determine persons possibly stricken by the infectious disease.

## § 12

### Legal relations in healthcare provision

(1) A legal relation subject of which is healthcare provision is established upon the healthcare provision agreement concluded between a person and a provider.

(2) A provider may refuse proposal for agreement on healthcare provision if

(a) conclusion of such agreement makes him go beyond its bearable workload,

(b) a personal relation of a medical worker to the person being provided with the healthcare cannot guarantee objective assessment of health condition of the person or

(c) healthcare provision is prevented by personal belief of a medical worker, who is to provide the healthcare.

(3) Reasons set out in subsection 2 part c) shall apply to artificial abortion, sterilization and assisted reproduction only.

(4) If a provider refuses a proposal for agreement on healthcare provision on the grounds stipulated in

subsection 2, pertinent self-governing region upon the suggestion of the person shall check these circumstances and determine without undue delay the provider to conclude the agreement with the person. If the self-governing region detects the refusal of the proposal for agreement has not been justified the same provider having refused the proposal for agreement on healthcare provision can be determined to healthcare provision. The provider shall reside in the closest possible place from the residence or place of work of the person. The decision of the self-governing region doctor is binding for the provider.

(5) The refusal of proposal for agreement on healthcare provision has no bearing on the right of the person for emergency care provision.

(6) An agreement on general outpatient care provision shall be concluded in writing for at least six months; its original shall be a part of medical records and its copy shall be submitted to the person or to a legal representative of the person.

(7) The provider may withdraw the agreement as per subsection 6 on the grounds stipulated in subsection 2 part a) and b); the person provided with the healthcare may withdraw the agreement even without giving reasons. Agreement withdrawal must be submitted in writing.

(8) The agreement on general outpatient care provision ceases in the case of death of the person, cessation of the provider or the lapse of notice period when withdrawing the agreement.

## § 13

### Healthcare-related services

Healthcare-related services are

(a) board provision within inpatient care provision,

(b) bed provision within inpatient care provision,

(c) processing of data ascertained upon the provision of inpatient care in electronic form for the purposes of health insurance,

(d) the statistic processing of medical prescription and repository order<sup>15)</sup> for the purposes of health insurance,

(e) transport,

(f) the stay of an escort of the person in inpatient care,

(g) the preparation of a medical appraisal,

(h) provision of an excerpt from medical records as per § 24 subsection 4.

## § 14

### Transport

(1) A transport pursuant to § 13 part e) besides emergency transportation, which is a part of emergency care (§ 2 subsection 3) includes the transportation

(a) of a person into the healthcare facility and between healthcare facilities for the purposes of healthcare provision and from the healthcare facility after the healthcare being provided,

(b) of biological material designated for diagnostic examination,

(c) of blood and transfusional medications,

(d) of organs, tissues and cells for the purposes of transplantation,

(e) of an escort as per part a) or an escort of a person in inpatient care.

(2) Transport of arrested or imprisoned person is secured by the Prison and Judicial Guard.

(3) Transport of a person in a police custody cell is secured by the Police Force; this shall not apply if the life and health protection of the person requires emergency care provision.

## § 15

### Escort of a person in inpatient care

(1) Escort of a person in inpatient care is a person taken into inpatient care together with the person being provided with the inpatient care.

(2) An escort of a person in inpatient care can only be an adult person;<sup>16)</sup> this shall not apply if the escort is a child up to three years of age taken into inpatient care together with the parent or an under-aged parent taken into inpatient care together with the child up to one year of age.

## § 16

### Medical appraisal

(1) A medical appraisal for the purposes of this Act is an appraisal result of

(a) health competence for performing specific activity,

(b) health condition in connection with entitlement of occupational illness,

(c) pain and social discrimination in case of injuries, occupational illnesses and other health damages.<sup>17)</sup>

(2) Medical appraisal is issued by the provider and appraisal as per subsection 1 is performed by a doctor determined by the provider.

(3) Medical appraisal is performed upon the request of an involved person or upon the request of a legal entity after the approval of such person.

## § 17

### Decision-making in healthcare and healthcare-related services provision

(1) If the person believes the healthcare has not been provided properly (§ 4 subsection 3) or the decision

of attending medical worker in connection with healthcare or healthcare-related services has not been correct the person is entitled to request a remedy from the provider; the request must be in writing.

(2) The provider is obliged to notify the applicant without undue delay on the fulfilment of the request.

(3) If the provider does not accommodate the request or does not notify the applicant without undue delay on the fulfilment of the request, the person is entitled to

(a) ask the Health Care Surveillance Authority (hereinafter “Authority”) for the performance of surveillance as per a separate regulation<sup>18)</sup> if the subject of the request is a proper healthcare provision,

(b) appeal to the surveillance executive body as per a separate regulation,<sup>19)</sup> if the subject of the request is other decision of attending medical worker in connection with healthcare or healthcare-related services provision.

## PART THREE

### MEDICAL RECORDS

#### § 18

##### Processing, providing and enabling of medical records data

(1) The provider is obliged to process, provide and enable the medical records data in line with this Act and a separate regulation.<sup>20)</sup>

(2) The approval of infringed person with processing, providing and enabling of medical records data is not required under the conditions stipulated in this Act.

(3) Whoever is provided or enabled with medical records data pursuant to this Act is obliged to uphold

confidentiality on it and to ensure its protection against loss or abuse.

#### § 19

##### Maintaining of medical records

(1) Maintaining of medical records means acquisition, collecting and recording of data pursuant to subsection 2.

(2) Medical records contain

(a) personal data of a person being provided with the healthcare in a necessary scope for identification of the person and detection of anamnesis of such person,

(b) information on instructions and informed approval (§ 6),

(c) data on the disease of the person, on the development and results of examinations, treatment and other significant circumstances connected with the health condition of the person and processes of healthcare provision,

(d) data on the scope of provided healthcare,

(e) data on healthcare-related services,

(f) data on temporary work incapability due to illness or injury and circumstances significant for appraisal of the health competence for performing work,

(g) epidemiologically significant circumstances,

(h) identification data of the pertinent health insurance company,

(i) identification data of the provider.

(3) Medical records as a whole are maintained by a general practitioner. Other attending medical worker maintains medical records to the scope of the healthcare provided by him/her.

(4) In the case of a woman who has made a written application for nondisclosure of her identity in connection

with the delivery (§ 11 subsection 10) special medical records are maintained to the scope of healthcare connected with her pregnancy and delivery a part of which is a personal data of the woman necessary for detection of anamnesis and data stipulated in subsection 2 part b) to i). Personal data necessary for her identification are maintained separately from special medical records together with the written application pursuant to § 11 subsection 10. Special medical records shall be appended with these data and sealed as a whole.

(5) The provider is obliged to maintain special medical records including personal data necessary for identification separately from medical records of other persons. The provision of § 24 subsection 4 and § 25 shall not apply to special medical records.

## § 20

### Maintaining forms of medical records

(1) Medical records are maintained in written form or in electronic form with secured electronic signature<sup>21</sup>) (hereinafter “electronic signature”).

(2) Medical records in electronic form with electronic signature are maintained in a record medium device in a text, graphic or audiovisual form.

(3) Medical records can be maintained in electronic form with electronic signature only if

(a) backup copies of data files are made at least once in each work day,

(b) accurate recordings are maintained on backup copies of data files which are stored in a place available only to persons authorised to make backup copies,

(c) a copy is made from the archived data and these are removed from an old medium before expiry of a writing on archive medium,

(d) archive copies are made at least once a year and the procedure of making the archive copies disables additional intervention taken later.

## § 21

### Reports in medical records

(1) Report in medical records contains

(a) the date and time of the report,

(b) instructive method, content of instruction, rejection of instruction, informed approval, rejection of informed approval and abjuration of informed approval,

(c) the date and time of provided healthcare, if different from the date and time of report,

(d) the scope of provided healthcare and healthcare-related services,

(e) results from other examinations if they are a part of provided healthcare the report of which is being taken,

(f) identification of attending medical worker,

(g) identification of a person being provided with the healthcare.

(2) Identification of an attending medical worker is demonstrated in medical records maintained in written form by name, surname, seal stamp and attending medical worker signature, in medical records maintained in electronic form by electronic signature of an attending medical worker.

(3) Report in medical records must be truthful and readable.

(4) Correction of report in medical records is performed by a new report consisting of correction date, report correction wording and identification of attending medical worker performing the correction. Report correction can only be performed by a medical worker which performed the original report; original report must remain readable.

## § 22

### Securing and archiving of medical records

(1) Securing and archiving of medical records is the responsibility of the provider. The provider is obliged to store and protect medical records in a way preventing its damage, loss, destruction or abuse even within duration of its archiving pursuant to subsection 2.

(2) Medical records maintained by a general practitioner are archived by the provider for the period of 20 years after death of a person; the rest of medical reports for the period of 20 years from the date of the last provided healthcare.

(3) The provider is obliged to secure the access to medical records for attending physician and medical workers to the necessary scope only.

## § 23

### Handover and deposit of medical records

(1) When changing the provider in case of general outpatient provision agreement withdrawal (§ 12 subsection 7) the provider is obliged to demonstrably deliver medical records or their copy by 7 days from the request to the new provider having concluded agreement on general outpatient care provision with the person.

(2) In the case of temporarily suspended licence for execution of individual medical practice<sup>22)</sup> and temporarily suspended permit for operation of healthcare facility<sup>23)</sup> the provider is obliged without undue delay to allow deposit of medical records to a doctor of a pertinent self-governing region; in the case of cancelled licence for the execution of individual medical practice or a permit for healthcare facility operation the one with cancelled licence or permit is obliged to allow deposit of medical records.

(3) After the cessation of licence for execution of individual medical practice<sup>24)</sup> and cessation of permit for healthcare facility operation<sup>25)</sup> each person with access to medical records is obliged

(a) to notify without undue delay the doctor of a pertinent self-governing region on these circumstances, to negotiate the procedure of medical records handling and to allow without undue delay a doctor of a pertinent

self-governing region to deposit the records,

(b) to protect the medical records in a way to prevent their damage, loss, destruction or abuse by the time of handling by a doctor of self-governing region.

(4) A doctor of a pertinent self-governing region which has taken the medical records in deposit pursuant to subsection 2 and 3 shall immediately deliver the medical records to the provider having concluded agreement on general outpatient healthcare provision with the person.

(5) The provider is obliged to deliver without undue delay the special medical records (§ 19 subsection 4) by six weeks from the day of delivery to the Ministry of Health [§ 45 part p)] if the woman by the said term did not abjure her application for nondisclosure of her identity in writing.

(6) In the process of delivery of the medical records pursuant to subsections 1 to 5 the records cannot be damaged, destroyed nor abused.

## § 24

### Providing of medical records data

(1) Medical records data are to be provided in the form of an excerpt from the medical records. Excerpt from the medical records shall, besides data stipulated in § 19 subsection 2 part a), h) and i), contain

(a) a chronological description of health condition development,

(b) a review of treatment up to date,

(c) data necessary for further healthcare provision,

(d) date of issue and identification of attending medical worker.

(2) General practitioner is obliged without undue delay to provide excerpt from the medical records to other medical worker in the scope of his/her request. When sending the person for further healthcare

provision the practitioner provides the excerpt from the medical records at his/her own incentive.

(3) Attending medical worker is obliged to provide the excerpt from the medical records to the extent of healthcare provided by himself/herself to the general practitioner immediately after the provision of healthcare and on request even within the duration of the providing of healthcare.

(4) The provider is obliged to provide an excerpt from the medical records on the grounds of written request in the scope of the request to

(a) a doctor of a territorial military administration for the purposes of regular enlistment,<sup>26)</sup>

(b) a pertinent authority<sup>27)</sup> for the purposes of social assistance, state social allowances or employment services as per separate regulations,<sup>28)</sup>

(c) a labour inspectorate<sup>29)</sup> and surveillance authorities as per separate regulations<sup>30)</sup> for the purposes of work injury or occupational disease investigation,

(d) the pertinent authority for the purposes of international adoption,<sup>31)</sup>

(e) persons entitled to examine the medical records if the extent of request does not exceed the extent of enabling of medical records data for them as per § 25 subsection 1.

## § 25

### Enabling of medical records data

(1) Medical records data are enabled in the form of examination of medical records of a person to

(a) the person himself/herself or a legal representative of the person in full,

(b) a husband or wife, child or a parent or their legal representative after the death of the person, this to full extent; in case there is no such person, to an adult person<sup>16)</sup> sharing

home<sup>32)</sup> with the person in time of the death, a relative<sup>33)</sup> or their legal representative,

(c) a person empowered on the basis of a written power of attorney<sup>34)</sup> as per part a) or b) with certified signature as per a separate regulation<sup>35)</sup> to the necessary extent determined in the power of attorney,

(d) an inspection doctor of a pertinent health insurance company for the purposes of inspection activities<sup>36)</sup> in full,

(e) Surveillance Authority for the purposes of surveillance of healthcare<sup>37)</sup> in full,

(f) an appraisal doctor for the purposes of medical appraisal activities upon execution of social insurance and in social security of policemen and soldiers as per separate regulations<sup>38)</sup> in full,

(g) an advisor established by a court, recruited by a criminal authority or requested upon execution of expert appraisal by one of the parties for the purposes directly connected with civil legal or criminal proceeding to the extent necessary for execution of expert appraisal; the extent of data necessary for execution of expert appraisal is under the competence of an advisor,

(h) the health insurance company performing individual health insurance as per a separate regulation<sup>39)</sup> for the purposes of inspection activities of provided healthcare related to insurance payment,

(i) the pertinent body of a professional organization to the extent of inspection of pertinent medical profession performance.

(2) A person entitled to examine the medical records has a right to make excerpts or copies from the medical records to the extent stipulated in subsection 1.

(3) The provider can reject examination of medical records to the person being provided with the healthcare in the specialized field of psychiatry or clinical psychiatry if this negatively affects his/her treatment.

(4) Each person is entitled to seek court protection if he/she believes that the examination of the medical records has been rejected unjustly.

(5) Medical records data are made available for the advisor [subsection 1 part g)] in the form of delivery on the grounds of an advisor request and approval of a prosecutor for the purposes of authenticity and completeness of data verification including verification of seal stamp and medical worker signature authenticity in medical records.

(6) Prior to delivery of medical records or its part as per subsection 5 the provider is obliged to secure the creation of a copy of the medical records or its part. Each page of the copy shall be signed by an advisor and a medical worker and the readable name, surname, date of delivery and seal stamp shall be added to their signatures. A copy of a part of the medical records shall be filed into original medical records.

(7) An advisor may not notify the person who requested the execution of expert appraisal on the medical reports data with the exception of data which become a necessary part of the expert appraisal.

## PART FOUR

### HEALTHCARE IN SPECIFIC CASES

#### CHAPTER ONE BIO-MEDICAL RESEARCH

##### § 26

#### General conditions

(1) Bio-medical research includes every research activity in the field of biology, medicine, pharmacy, nursing care, midwifery and psychology which can influence physical or mental health of a person taking part in this research (hereinafter “research participant”).

(2) Bio-medical research can be performed only under the conditions stated in this law and in a separate regulation.<sup>9)</sup>

(3) Bio-medical research is performed freely with respect to the right to protect one’s dignity, physical and mental integrity [§ 11 subsection 8 part a)], safety and legitimate interests of the research participant. Interests of the research participant always take precedence over interests of science and research.

(4) Bio-medical research can be performed only if there is no comparable effective alternative and such research

(a) is scientifically justified,

(b) meets generally accepted criteria of scientific quality,

(c) is performed under the management of a qualified research worker in accordance with the pertinent scientific and ethical principles,

(d) must be reviewed and approved as per this Act or a separate regulation.<sup>9)</sup>

(5) Bio-medical research is approved by

(a) an inpatient care provider in an inpatient medical care facility after being carefully reviewed and positively judged by Ethical commission [§ 5 subsection 1 and subsection 2 part c)],

(b) a self-governing region in an outpatient medical care facility under the territorial scope of which the facility operates after being carefully reviewed and positively judged by Ethical commission [§ 5 subsection 1 and subsection 2 part b)],

(6) If the bio-medical research is to be performed in several inpatient medical care facilities, its reviewing and approval as per subsection 5 part a) is preceded by its investigation and review by Ethical commission established by an inpatient care provider which is a coordinative subject in this research.

(7) If the bio-medical research is to be performed in several outpatient medical care facilities on the territory of more than one self-governing region, its performance shall be reviewed and approved by the self-governing region under whose the territorial scope the coordinative

subject of this research operates.

(8) The bio-medical research expected to bring a direct benefit for physical or mental health of a research participant (hereinafter “medical indication based research”) cannot include risks disproportional to its expected benefit.

(9) Bio-medical research not expected to bring direct benefit for the physical or mental health of a research participant (hereinafter “research without medical indication”) can be performed only if the risk or burden the research participant must carry is acceptable for the research participant.

(10) It is not allowed to perform the research without medical indication on

- (a) a living foetus or an embryo,
- (b) an arrested or imprisoned person,
- (c) a soldier of compulsory military service, alternative or preparatory service or a person performing civilian service,
- (d) a person under the impatient care as per § 6 subsection 8 part c),
- (e) a foreigner.

## § 27

(1) Conditions for participation in the bio-medical research are met after the submission of written approval prior to instructions. Such written approval must contain the date of issue and a signature of the future bio-medical research participant or his/her legal representative.

(2) The instructions prior to informed approval must be provided as per § 6 subsection 2 and must contain information on

- (a) the possibility for the research participant to cancel his/her approval anytime even without giving reason,

(b) the purpose, scheduled plan, assumed risks and expected benefit,

(c) the nature, scope and duration of all performances and steps necessary to take in this research, especially the ones describing the assumed risks and burden,

(d) other available preventive, diagnostic and treatment procedures,

(e) measures intended for solving undesirable physical or mental reactions which the research participant may suffer in connection with this research, or for answering possible questions of research participants,

(f) measures intended for ensuring privacy and protection of personal information of research participants,

(g) measures intended for ensuring that the information on health condition of a research participant gained in connection with his/her participation in this research are used for the betterment or preservation of his/her health,

(h) measures intended for ensuring adequate compensation in the case of damage of the health of the research participant in connection with his/her participation in this research,

(i) the expected use of results, data or biological materials gained during this research including their planned commercial use,

(j) opinion of Ethical commission,

(k) financial resources for this research.

(3) The refusal to participate in the bio-medical research, informed approval of the research participant or its cancellation must not adversely affect provision of healthcare or represent other adverse consequences for the research participant on the part of medical practitioners.

## § 28

### Review of ethical acceptability of a bio-medical research project

(1) The purpose of review of ethical acceptability of a bio-medical research project is above all to ensure the right to protect one's dignity, to respect physical and mental integrity, safety and legitimate interests of the research participant (§ 26 subsection 3). The purpose of the review is to eliminate the possibility of inadequate influence or applying pressure to force the person to participate in the research. Special attention must be paid to persons incapable to give an informed approval (§ 32) and to persons unable to give an informed approval due to their health condition (§ 34).

(2) Review of ethical acceptance of bio-medical research project must be based on adequate expertise and experience of Ethical commission members. When reviewing scientific, legal and ethical aspects of a planned bio-medical research, the scientific-specialist viewpoint and the viewpoint of the Ethical commission members without professional qualification to perform medicine or research must be taken into account.

(3) Ethical acceptability of a bio-medical research project is reviewed on the basis of information included in complete written documentation of this project submitted to Ethical commission for investigation and review by a person responsible for planning and implementation of this project (hereinafter "executive researcher"); in the case of bio-medical research that is a clinical checking of pharmaceuticals as per a separate regulation on the basis of the protocol<sup>40</sup>) submitted to Ethical commission by the sponsor.

(4) Before issuing its standpoint, the Ethical commission can request complementation of documentation of the reviewed bio-medical research project considered to be necessary for review of this project, or suggest modifications of the reviewed project and its documentation considered necessary from the viewpoint of its ethical acceptability.

(5) Ethical commission issues its standpoint on ethical acceptability of the bio-medical research project within 90 days from the submission of complete written documentation of the project.

(6) Ethical commission, the executive researcher and the person approving bio-medical research performance (§ 26 subsection 5 to 7) are obliged to adopt measures for ensuring protection of confidential information contained in the documentation.

## § 29

### Security and health protection of research participants

(1) When planning and performing bio-medical research, the executive researcher is obliged to apply all necessary measures for ensuring security and reduction of risk and burden of research participants.

(2) Bio-medical research can be only performed under a close supervision of a doctor with appropriate professional qualification and experience. Bio-medical research in nursing care can only be performed under a close supervision of a nurse with appropriate professional qualification and experience; bio-medical research in midwifery can only be performed under a close supervision of a midwife with appropriate professional qualification and experience.

(3) Before including a participant into a bio-medical research, the doctor is obliged to evaluate health condition of each participant and take necessary examinations aimed to reveal increased risk in connection with his/her participation in this research.

(4) If a woman in reproductive age is a participant in this research, the doctor is obliged to pay special attention to possible adverse influence in connection with her participation in this research for her actual or future pregnancy and for the health of her conceived or born child.

(5) Participation in bio-medical research may not delay or disable provision of necessary healthcare to the research participant.

(6) Verified healthcare procedures must be provided to research participants assigned to control groups.

(7) Use of placebo is allowed only in cases where there are no verified methods or in cases where abortion or omission of such methods does not constitute

unacceptable risk or burden for a research participant.

(8) As per subsection 7, placebo is a form of treatment with no specific influence on treated condition to simulate effective treatment and eliminate errors of a researcher in a controlled experiment.

### § 30

#### **Supervision over the course of bio-medical research and procedures taken upon identification of new substantial knowledge**

(1) The executive researcher is obliged to notify the person who approved the bio-medical research (§ 26 subsection 5 and 7) in written form and the Ethical commission on its development in determined time periods, at least once a year.

(2) If new scientific knowledge, substantial undesirable events or other facts relevantly modifying conditions of this research are identified, the executive researcher is obliged to notify without undue delay the person who approved the bio-medical research and the Ethical commission and propose all necessary measures.

(3) If security or health of research participants is threatened, the executive researcher is obliged to immediately ensure all necessary measures.

(4) Immediately upon receiving the information as per subsection 2 the person who approved the bio-medical research (§ 26 subsection 5 and 7) is obliged without undue delay to re-evaluate the decision on approval of the bio-medical research. If necessary, the person is obliged without undue delay to make a decision on abortion or stopping the bio-medical research. The pertinent Ethical commission is obliged to take a stand to the information as per subsection 2 at its nearest meeting.

(5) The executive researcher is obliged to notify the research participants or their legal representatives immediately about the new facts as per subsection 2 and about adopted measures, and if necessary, to ask the research participants for their informed approval in order to proceed in the bio-medical research.

(6) The executive researcher is obliged without undue delay to notify the person who approved the bio-medical research and the Ethical commission about the abortion or early stopping of the bio-medical research and about the reasons for it.

### § 31

#### **Disposal with new scientific information and knowledge on the health condition of the bio-medical research participants**

(1) If during the bio-medical research new information substantial from the point of view of current or future health or quality of life of a research participant, these will be provided to the participant upon his/her consent in appropriate time.

(2) After the end of the bio-medical research, the executive researcher is obliged to notify in written form the person who approved the bio-medical research (§ 26 subsections 5 to 7) and the Ethical commission on the development and results of the bio-medical research. The results of the bio-medical research are to be made available to the participants upon their request after the evaluation of the research.

(3) The executive researcher is obliged to publish the results of the bio-medical research in appropriate time and in an appropriate way.

### § 32

#### **Bio-medical research with participation of persons incapable of giving an informed approval**

(1) Medical indication based research with participation of a person incapable of giving an informed approval can be performed only in case that

(a) the research with comparable effectiveness cannot be performed with the participation of a person capable to give an informed approval,

(b) the person was informed about this research and about his/her rights and legal measures for

their protection in a way adequate to his/her health condition and mental abilities,

(c) the person does not express evident disapproval with his/her participation in this research in a way adequate to his/her abilities to express disapproval regarding his/her physical and mental condition.

(2) Research without medical indication with participation of the person incapable of giving an informed approval can be exceptionally performed in the case that, besides conditions as per subsection 1, the following conditions are met:

(a) the objective of the research is to achieve results bringing benefit for other persons in the same or similar condition, suffering from the same or similar illness or handicap,

b) the research represents for the participant only

1. a risk that according to the current state of scientific knowledge constitutes only low and short-term negative influence on the health condition of the research participant (hereinafter “minor risk”) or
2. a burden with only a low and short-term inconvenience (hereinafter “minor burden”).

(3) Bio-medical research with the participation of a person incapable of giving an informed approval can only be performed on the basis of an informed approval of the legal representative of the future research participant.

### § 33

#### **Bio-medical research with the participation of pregnant or suckling woman**

(1) Medical indication based research with participation of pregnant or suckling woman can be performed only in case that

(a) the research with comparable effectiveness cannot be performed with the participation of a woman who is not pregnant nor suckling,

(b) the objective of the research is to achieve results bringing benefit to other women in relation to reproduction or to other conceived or born children,

(c) expected benefit from the research does not constitute risks disproportional to its expected benefit for participating woman and for her conceived or born child,

(d) when evaluating scientific and ethical aspects of this research, the participant of the research is considered to be the woman as well as her conceived or born child.

(2) Research without medical indication with the participation of pregnant or suckling woman can be performed only in case that

(a) the research with comparable effectiveness cannot be performed with the participation of a woman who is not pregnant nor suckling,

(b) the objective of the research is to achieve results bringing benefit to other women in relation to reproduction or to other conceived or born children,

(c) the research represent for the woman only a minor risk or burden [§ 32 subsection 2 part b)],  
d) any assumed adverse influence on the health of a conceived or born child is prevented.

### § 34

#### **Bio-medical research with the participation of a person in condition requiring emergency care**

(1) Medical indication based research with the participation of a person in a condition requiring emergency care (§ 2 subsection 3) and who is, with respect to his/her health condition, unable to give an informed approval or such approval is not possible to gain on time due to urgency from his/her legal representative can be only performed in the case that

(a) the research with comparable effectiveness cannot be performed with the participation of a

person not requiring emergency care,

(b) the project of this research has been reviewed and approved also for participation of persons requiring emergency care,

(c) approval is presumable,

(d) the objective of the research is to achieve results bringing benefit for other persons in the same or similar condition, suffering from the same or similar illness,

(e) the research represents for the participant only a minor risk or burden (§ 32 subsection 2 part b).

(2) The executive researcher is obliged to ensure notifying of the bio-medical research participants as per subsection 1 or notifying of their legal representatives about participation in this research as soon as possible. Proceeding of the participation in the bio-medical research is possible only on the basis of an informed approval with the participation in bio-medical research (§ 27 subsection 1).

## CHAPTER TWO

### REMOVAL, CONSERVATION AND TRANSFER OF ORGANS, TISSUE AND CELLS

#### § 35

##### General conditions

(1) Removal, conservation and transfer of organs, tissue and cells for the transplantation and scientific research purposes can be performed by providers on the basis of a license as per a separate regulation.<sup>4)</sup> For the purposes of this Act a recipient is a person receiving an organ, tissue or cells into his/her body.

(2) For the purposes of this Act a donor is a living or dead person from whose body organs, tissue or cells are removed for the transplantation and scientific research purposes.

(3) Providers as per subsection 1 establish

(a) transplantation centre executing performances connected with removal, distribution and transfer of organs to the recipient,

(b) removal centre executing performances connected with removal and distribution of organs,

(c) tissue bank executing performances connected with removal, treatment, conservation and distribution of tissue and cells for the purposes of transplantation.

(4) Inpatient care provider is obliged to notify the donor register managed by the Ministry of Health [§ 45 part o)] on potential donors.

(5) Removed organ and tissue must be expertly bioptically examined before the transplantation.

(6) International cooperation regarding the exchange of organs, tissue and cells can be performed only with reputable international organisations upon written agreement and after the approval of the Ministry of Health.

(7) Removal and transfer of organs, tissue and cells for financial profit or other asset profit is banned.

#### § 36

##### Removal of organs, tissue and cells from the bodies of living donors

(1) Removal of organs, tissue and cells from the body of a living donor for the purposes of their transfer to the body of another person can be made only if

(a) removal is expected not to seriously endanger the health condition of the donor,

(b) direct healing benefit for the recipient is expected,

(c) the benefit for the recipient prevails over the detriment of the donor,

(d) a suitable organ, tissue or cells cannot be obtained from a dead donor,

(e) no other better or comparable alternative treatment procedure is known.

(2) As per subsection 1 the donor can only be a person fully capable of executing legal acts<sup>41</sup>), who was duly instructed and subsequently gave written informed approval. As per subsection 1 a person unapt to give an informed approval can become a donor on the basis of an informed approval of his/her legal representative if

(a) the removal relates to regenerative tissue,

(b) a suitable donor capable to give an informed approval is not available,

(c) the potential recipient is a brother or a sister of the donor,

(d) the donation has a life-saving potential for the recipient.

(3) As per subsection 1 the donor cannot be a person who is arrested or imprisoned.

(4) Board of consultants of the transplantation centre shall review whether the successful completion of organ or tissue removal and its transfer to the recipient can be reasonably assumed and consider the fulfilment of conditions as per subsection 1. The removal cannot be performed if the serious jeopardy to the health condition of the donor is assumed even though the person gave informed approval.

(5) The organ or tissue removal for the purposes of transfer into the body of a person genetically related to the donor can be made only upon approval of the board of consultants of the transplantation centre. The organ or tissue removal for the purposes of transfer into the body of a person remotely genetically related to the donor or a person not related genetically to the donor can be made only upon approval of the board of consultants determined for this purpose by the Ministry of Health.

## § 37

### Removal of organs, tissue and cells from bodies of dead donors

(1) The dead donor can only be a person announced dead as per this Act (§ 43).

(2) Removal of organs, tissue or cells from the body of a dead donor can only be made in case the person during his/her life did not make a written declaration on disapproval with such intervention into his/her physical integrity. For the person unapt to give such an informed approval, his/her legal representative is entitled to make such written declaration during his/her life.

(3) The declaration as per subsection 2 with certified signature as per a separate regulation<sup>35</sup>) is sent to the registry of persons declaring their disapproval with post-mortal removal of their organs, tissue and cells, which is maintained by the Ministry of Health § 45 part o).

(4) Disapproval as per subsection 2 can be withdrawn anytime; the withdrawal of disapproval must meet conditions as per subsection 3.

(5) Prior to the removal of organs, tissue or cells from the body of a dead donor the provider is obliged to

(a) verify his/her identity,

(b) check the register of persons as per subsection 3 due to the possibility of the declaration of disapproval.

(6) After the removal of organs or tissue from the body of a dead donor autopsy<sup>14</sup>) must be performed in all cases. The report on removal of organs shall be added to the autopsy record.

## § 38

### Transfer of organs, tissue and cells to the recipient

(1) The transfer of an organ, tissue or cells into the body of a recipient can only be performed if the

recipient is in a favourable health condition for such an operation; the operation must be approved by means of a written informed approval following instructions.

(2) Whether the health condition of the recipient is favourable or not is reviewed by attending physician and a doctor from the transplantation centre.

(3) Registry of transplantation candidates is maintained by the Ministry of Health [§ 45 part o)].

(4) Selection of the recipient is governed strictly by medical considerations.

### § 39

#### **Taking blood for transfusion and preparation of transfusional medications**

(1) A blood donor can only be a person fully capable of executing legal acts, over 18 years of age.

(2) Taking blood for transfusion and preparation of transfusional medications can be performed only if

- (a) it is preceded by an informed approval,
- (b) prior to the blood taking all necessary blood donor examinations are performed,
- (c) the health condition of the blood donor is not endangered and
- (d) there is no health contraindication for blood taking.

### CHAPTER THREE

## STERILIZATION

### § 40

#### **Sterilization**

(1) For the purposes of this Act sterilization is a prevention of fertility without removing or damaging sex

glands.

(2) Sterilization can only be performed pursuant to the written application and a written informed approval following instructions given to the person fully capable of executing legal act or a legal representative of the person unapt to give an informed approval amended by a written application and informed approval of the person unapt to give an informed approval and a ruling of a court pursuant to the application of the legal representative.

(3) The instructions prior to informed approval must be provided as per § 6 subsection 2 and must contain information on

- (a) alternative methods of contraception and family planning,
- (b) possible changes of life circumstances leading to the application for sterilization,
- (c) medical consequences of sterilization as a method, objective of which is an irreversible prevention of fertility,
- (d) possible failure of sterilization.

(4) The application for sterilization is submitted to the provider of sterilization. The application for sterilization of a woman is reviewed and sterilization itself is performed by a doctor specializing in the specialized field of gynaecology and obstetrics, the application for sterilization of a man is reviewed and sterilization itself is performed by a doctor specializing in the specialized field of urology.

(5) Sterilization cannot be performed earlier than 30 days after the informed approval was expressed.

### PART FIVE

## PROCEDURES TAKEN IN THE CASE OF DEATH

## § 41

### Notification on death

(1) Whoever has received any information on death outside a medical facility or has found a dead body is obliged to notify the nearest provider without undue delay; this shall not apply if he/she notified the Police force or attending physician.

(2) The provider is without undue delay obliged to notify on the death being notified of as per subsection 1 and the death in a medical facility to

(a) persons related<sup>33)</sup> to the dead person and if these persons are unknown, to the municipality pursuant to the permanent address or temporary address of the dead person, if neither the permanent nor the temporary address is known, to the municipality where the medical facility being notified of the death as per subsection 1 or in which the death occurred operates,

(b) the Health Care Surveillance Authority.<sup>42)</sup>

(3) The provider is also obliged to notify the pertinent Police force on the death of a person in a medical facility being treated in connection with injury, or health damage caused by another person or by poisoning.

## § 42

### Examination of the dead body

(1) Examination of the dead body identifies the death, time and cause of death.

(2) Examination of the dead body is performed by a doctor entrusted by the Health Care Surveillance Authority. Every person is obliged to provide information on circumstances of the death to the doctor examining the dead body.

(3) The doctor performing examination of the dead body is obliged to notify the pertinent civil registry without undue delay on the death;<sup>43)</sup> in the case of

suspicion that the death was caused by criminal act or suicide or in the case of death of a foreigner to the pertinent Police force as well.

(4) Autopsy can be ordered after the examination of the dead body only under conditions stipulated as per a separate regulation.<sup>14)</sup>

## § 43

### Identification of the death

(1) A doctor is obliged to detect death in accordance with current scientific knowledge.

(2) The person is deemed dead if the doctor detects permanent stopping of breathing and heart activity.

(3) The person is deemed dead in case of irreversible extinction of all functions of the whole brain (hereinafter “brain death”) as well.

(4) If breathing and circulatory functions are being maintained by means of life support machines, the brain death must be confirmed by unanimous approval of the board of consultants (§ 2 subsection 5).

(5) The board of consultants must include the attending physician, a doctor specializing in the specialized field of neurology and a doctor specializing in the specialized field of anaesthesiology and intensive medicine or a doctor specializing in the specialized field of anaesthesiology and resuscitation<sup>44)</sup> as per subsection 4. A doctor from the transplantation group to perform transplantation cannot be a member of the board of consultants.

(6) Once the brain death is detected by the board of consultants, the attending physician is obliged to discontinue resuscitation with the exception of resuscitation after brain death detection proposed by the board of consultants due to removal of an organ, tissue or cells for the purposes of transplantation.

(7) The doctor or the board of consultants are obliged to draw up a record on identification of death immediately.

(8) Once death is detected by a doctor or the board of consultants, the dead body can only be subjected to:

- (a) an autopsy,<sup>14)</sup>
- (b) healthcare performances for the purposes of removal of organs, tissue and cells (§ 37),
- (c) healthcare performances leading to birth in the case of a pregnant woman.

## PART SIX

### INFORMATION SYSTEM OF THE HEALTH SECTOR

#### § 44

(1) Information system of the health sector consists of healthcare information systems and their operators and binding standards for healthcare informatics and statistics (hereinafter “binding standards”).

(2) Healthcare information systems are packages of software, hardware and other means of record keeping, control, processing and providing health sector related data.

(3) Binding standards are means of comparability, information communication technologies, structures and formats of data interfaces, structure, quality, time and method of data recording and data provision and other standardized regulations and procedures. Data recorded in healthcare information systems must be comprehensible, clear, documented and must provide a truthful reflection of recorded facts. Binding standards shall be established by the Ministry of Health by means of generally binding legal regulation.

(4) The provision of subsection 3 does not affect the means of comparability and standards issued or declared by the Statistical Office of Slovak Republic as per separate regulations.<sup>45)</sup>

(5) To protect confidential information in healthcare information systems, their operators follow

a separate regulation.<sup>15)</sup>

(6) To protect personal information in healthcare information systems, their operators follow a separate regulation<sup>20)</sup>. A list of personal information for healthcare information systems operators entitled to gain and process, the purpose of their processing, the conditions of their gaining and affected persons is listed in Annex 2.

(7) Legal entities in the jurisdiction of the Ministry of Health, providers, health insurance companies, Public Health Institute of SR and regional offices of public healthcare<sup>46)</sup> and the permit issuing authority as per a separate regulation<sup>47)</sup> are obliged

(a) to use and follow the binding standards as per subsection 3 when operating healthcare information systems,

(b) to provide statistical and other data within the scope stipulated as per a separate regulation to the Statistical Office of SR<sup>15)</sup>

c) to provide data recorded pursuant to part a) to the Ministry of Health for the purposes of creation and execution of national health policy and for the purposes of surveillance,

(d) to provide data pursuant to part a) to the Surveillance Authority<sup>42)</sup> for the purposes of surveillance,

(e) to produce materials and to provide an explanation to provided materials to the Ministry of Health at the request of Ministry of Health or Surveillance Authority by the deadline set by these authorities.

(8) Obligations pursuant to subsection 7 part (a) and (b) shall be applied to the Surveillance Authority<sup>42)</sup> as well.

## PART SEVEN

### EXECUTION OF STATE ADMINISTRATION

## § 45

The Ministry of HealthThe Ministry of Health as a central body of state administration in the healthcare sector within its authority

- (a) elaborates concepts of significant directions and priorities of state healthcare policy development,
- (b) expertly guides healthcare provision,
- (c) issues standard diagnostic and therapeutic practices,
- (d) governs national programmes with the objective of protection, preservation and recovery of health,
- (e) coordinates research activities in the healthcare sector and application of scientific research result in practice,
- (f) governs and controls education and teaching in healthcare education system<sup>48)</sup> in cooperation with the Ministry of Education of SR,
- (g) administers and controls healthcare universities,<sup>49)</sup>
- (h) administers further education of medical practitioners,<sup>50)</sup>
- (i) issues certifications on accreditation of specialized study programmes and on accreditation of certificated study programmes,<sup>51)</sup>
- (j) issues permits and other decisions on issues stipulated as per a separate regulation,<sup>4)</sup>
- (k) supervises healthcare provision as per a separate regulation,<sup>4)</sup>
- (l) serves as the pertinent authority in public health insurance for the coordination of material benefits of healthcare,
- (m) is the notification authority in further education of medical practitioners; notifies

European Commission, member states of EU and member states of EFTA on the list of diplomas, certificates and other documents on specializations and certifications issued in the Slovak Republic, which meet criteria stipulated as per a separate regulation<sup>52)</sup> including modifications and amendments of these documents, certificates and other documents on specializations and certificates, which do not meet stipulated criteria and within which education process was suspended,

- (n) elaborates the concept of development of information system of the health sector and integration and operates the information system,
- (o) maintains national health registers,
- (p) maintains and archives special medical records,
- (q) establishes Ethical commission for reviewing ethical issues rising in the field of healthcare provision including bio-medical research [§ 5 subsection 2 part a)],
- (r) establishes facilities for fulfilling special assignments in the field of health sector especially statistical, information and library facilities,
- (s) secures coordination of healthcare provision with other central bodies of state administration,
- (t) secures international cooperation in the field of healthcare provision,
- (u) guides transferred execution of state administration in the field of healthcare implemented by self-governing regions,
- (v) secures homogenous preparation of the health sector for the state defence.

## § 46

### Execution of local state administration in the health sector

(1) State administration in the field of health sector in self-governing region as transferred execution of state administration is executed by the self-governing region, which

(a) establishes Ethical commissions to examine the ethical admissibility of bio-medical research projects and the ethical issues arisen in outpatient care provision [§ 5 subsection 2 part b)],

(b) determines provider to a person when his/her proposal for agreement on healthcare provision was rejected (§ 12 subsection 4),

(c) deposits medical records and secures handover of medical records to another provider (§ 23 subsection 2 to 4),

(d) approves bio-medical research in an outpatient medical care facility (§ 26 subsection 5 part b) and subsection 7),

(e) secures substitution<sup>53)</sup> if healthcare provision by other providers is necessary and in the case of temporary suspension of a permit,

(f) issues permits and other decisions on issues stipulated as per a separate regulation,<sup>4)</sup>

(g) supervises healthcare provision within the extent stipulated as per a separate regulation,<sup>4)</sup>

(h) determines a doctor for the execution of recruitment,<sup>26)</sup>

(i) secures fulfilment of assignments laid by the Ministry of Health related to the health sector,

(j) cooperates with the Ministry of Health in securing homogenous preparation of health sector for the state defence.

(2) For the purposes of fulfilment of assignments in the field of health sector, the self-governing region determines the doctor of self-governing region and the nurse of self-governing region, who are appointed and withdrawn by the chairperson of the self-governing region after the approval of the Ministry of Health.

(3) The nurse of self-governing region fulfils assignments in the field of health sector in relation to nursing and midwifery care provision.

## PART EIGHT

### COMMON, INTERIM AND FINAL PROVISIONS

#### § 47

(1) Organisation of healthcare provision within the sphere of authority of the Ministry of Defence of the Slovak Republic, the Ministry of Interior of the Slovak Republic, the Ministry of Transport, Post and Telecommunication of the Slovak Republic and the Ministry of Justice of the Slovak Republic shall be regulated by central bodies of state administration by means of generally binding legal regulations issued upon agreement with the Ministry of Health.

(2) Organisation of healthcare provision in the Slovak Information Service and the National Security Office shall be governed by generally binding legal regulation issued by the Ministry of Interior of the Slovak Republic upon agreement with the Ministry of Health.

#### § 48

(1) Contracts on the provision of healthcare concluded pursuant to regulations to date are deemed contracts concluded as per this Act.

(2) Proceeding on the rights and obligations of natural persons in connection with healthcare provision, which have not been lawfully finished to the day when this Act acquires force shall be finished as per regulations to date.

#### § 49

Persons responsible for record-keeping and archiving of special medical records and persons who learn information from special medical records are obliged to

keep it confidential. Obligation of confidentiality can be removed only by court.

## § 50

The following regulations of the Ministry of Health of the Slovak Socialist Republic of 14 April 1972 No. Z-4582/1972-B/1 on the Execution of sterilization (registered in part 13/1972 Coll.) are hereby repealed.

### Article II

Act No. 428/2002 Coll. on personal information protection pursuant to the wording of Act No. 602/2003 Coll. is hereby supplemented as follows:

1. In § 9 subsection 1 part e) reads:

„(e) this is processing for the purposes of healthcare provision and performing the public health insurance if this data is processed by a healthcare provider, health insurance company or the Health Care Surveillance Authority or”.

2. In § 9, subsection 1 is amended by part f), which reads:

„(f) this is processing of data in social insurance, social security of policemen and soldiers and in employment services if the data is processed by the Social insurance agency or other authority<sup>13a)</sup>.”

The footnote to reference 13a reads:

„<sup>13a)</sup> Act No. 328/2002 Coll. on Social security of policemen and soldiers and on the amendment and supplementing of certain laws, as amended.”

### Article III

The National Council of Slovak Republic Act No. 277/1994 Coll. on healthcare pursuant to the wording of

the National Council of Slovak Republic Act No. 98/1995 Coll., the National Council of Slovak Republic Act No. 110/1996 Coll., the National Council of Slovak Republic Act No. 222/1996 Coll., Act No. 140/1998 Coll., Act No. 241/1998 Coll., Act No. 80/2000 Coll., Act No. 416/2001 Coll., Act No. 553/2001 Coll., Act No. 118/2002 Coll., Act No. 131/2002 Coll., Act No. 219/2002 Coll., Act No. 450/2002 Coll., Act No. 457/2002 Coll., Act No. 138/2003 Coll., Act No. 445/2003 Coll., Act No. 528/2003 Coll., Act No. 578/2003 Coll., Act No. 215/2004 Coll., Act No. 377/2004 Coll. and ruling of the Constitutional Court of the Slovak Republic No. 396/2004 Coll. is hereby amended as follows:

1. § 1 to 20a, § 23 to 29, § 31 to 33b, § 35, 36 and § 36b to 58 are omitted.

2. In § 59 subsection 3 the word “declared” is replaced by the word “recognized”.

3. In § 59 subsection 5 the words “of the Ministry of Health” are replaced by the words “of the Ministry of Health of the Slovak Republic (hereinafter “the Ministry of Health”).

4. In § 65 subsection 2 the word “declare” is replaced by the word “recognize”.

5. In § 65 subsection 3 the word “declared” is replaced by the word “recognized”.

6. In § 65 subsection 4 to 10 the word “declaration” is replaced by the word “recognition”.

7. § 65 subsection 14 reads:

„(14) The Ministry of Health issues a generally binding legal regulation recognizing natural springs as a natural healing spring or a spring of natural springs of mineral water and declaring protection area of the spring or cancelling the recognition of a natural healing spring or a spring of natural springs of mineral water and declaring protection area if such a spring has lost the required attributes and effects as per subsections 2 and 3”.

8. In § 65 subsection 15 the word “declaration” is replaced by the word “recognition”.

9. In § 65a subsection 2 the word “declared” is replaced by the word “recognized”.

10. In § 65a subsections 4 and 5 read:

„(4) Only a natural water spring recognized as a natural healing spring can be used for filling the consumer packages and introduction in the market with identification “Natural healing water”.

„(5) Only natural water recognized as natural mineral water can be used for filling the consumer packages and introduction in the market with identification as per a separate regulation<sup>16a</sup>.”

The footnote to reference 16a reads:

<sup>16a</sup>) The National Council of the Slovak Republic Act No. 152/1995 Coll. on foodstuffs, as amended.

11. In § 65b subsection 6 part b) the word “declaration” is replaced by the word “recognition”.

12. In § 66 subsection 7 the word “declaration” is replaced by the word “recognition”.

13. In § 68 second sentence reads: “In the same way, the Ministry of Health can cancel the recognition of natural springs as natural healing springs or natural springs of mineral water or the declaration of climatic conditions favourable for healing if they have lost the attributes which made them recognized or declared.”

14. In § 69 subsection 1 part e) the words “shall declare” are replaced by the words “shall recognize” and the word “declare” is replaced by the word “recognize”.

15. In § 70 subsections 1 and 6 are omitted. Current subsections 2 and 3 are now indicated as subsections 1 and 2, subsection 5 is indicated as subsection 3 and current subsections 7 and 8 are now indicated as subsections 4 and 5.

16. § 71 reads:

„§ 71

(1) General regulations on administrative proceedings<sup>11</sup>) shall apply to proceedings and decisions as per this Act

(2) Permits to use natural springs of mineral water issued pursuant to regulations to date are deemed permits issued for using natural springs of mineral water as per

this Act.

(3) Natural healing waters and natural springs of mineral waters declared pursuant to regulations to date are deemed natural healing waters and natural springs of mineral waters recognized as per this Act.

17. § 72 and 73 are omitted.

18. § 74 reads:

„§ 74

The Ministry of Health

(a) indicates the measures for protection of natural treatment spas, natural healing waters, natural springs of mineral waters and climatic conditions favourable for healing and secures the surveillance of adherence to the protection,

(b) is an authorized body concerning recognition of natural springs of mineral waters imported from the third countries,

(c) is the notification authority concerning recognition of natural water as natural mineral water; notifies European Commission on natural waters recognized as natural mineral waters in the Slovak Republic and on natural mineral waters with cancelled recognition.”

19. § 74a, § 76 to 80b, § 80d to 80g, § 80i to 80m are omitted.

20. In § 75 part d) reads:

“d) reviews proposals for declaration of spa towns, proposals for recognition of natural springs as natural healing springs and natural springs of mineral waters, proposals for establishing natural treatment spas and for building facilities for using natural healing springs.”.

21. Annex 1 and Annex 2 are omitted.

22. The words “natural springs of mineral waters” in all their forms throughout the whole text of the Act are replaced by words “natural springs of mineral waters” in appropriate form.

#### *Article IV*

Act No. 140/1961 Coll. Criminal Code pursuant to the

wording of Act No. 120/1962 Coll., Act No. 53/1963 Coll., Act No. 184/1964 Coll., Act No. 56/1965 Coll., Act No. 81/1966 Coll., Act No. 148/1969 Coll., Act No. 45/1973 Coll., Act No. 43/1980 Coll., legal measure No. 10/1989 Coll., Act No. 159/1989 Coll., Act No. 47/1990 Coll., Act No. 84/1990 Coll., Act No. 175/1990 Coll., Act No. 457/1990 Coll., Act No. 545/1990 Coll., Act No. 490/1991 Coll., Act No. 557/1991 Coll., Act No. 60/1992 Coll., ruling of the Constitutional Court of Czech and Slovak Federative Republic issued in part 93/1992 Coll., the National Council of Slovak Republic Act No. 177/1993 Coll., the National Council of Slovak Republic Act No. 248/1994 Coll., the National Council of Slovak Republic Act No. 102/1995 Coll., the National Council of Slovak Republic Act No. 233/1995 Coll., the National Council of Slovak Republic Act No. 100/1996 Coll., Act No. 13/1998 Coll., Act No. 129/1998 Coll., Act No. 10/1999 Coll., Act No. 183/1999 Coll., Act No. 399/2000 Coll., Act No. 253/2001 Coll., Act No. 485/2001 Coll., Act No. 237/2002 Coll., Act No. 421/2002 Coll., Act No. 421/2002 Coll., Act No. 448/2002 Coll., Act No. 553/2002 Coll., Act No. 171/2003 Coll., Act No. 457/2003 Coll. and Act No. 403/2004 Coll. is hereby amended as follows:

§ 246b is inserted after § 246a which reads:

“§ 246b

Illegal sterilization

(1) Whoever sterilizes a natural person in discord with the Act shall be sentenced to prison for three years to eight years or prohibited to execute the activities or sentenced for statutory penalty.

(2) A perpetrator shall be sentenced to prison for five years in the case

(a) of committing a crime set forth in subsection 1 as a member of an organized group or

(b) of gaining substantial benefit for himself/herself or other person by committing a crime set forth in subsection 1.“

*Article V*

This Act shall acquire force on 1 January 2005.

President of the Slovak Republic

Chairman of the National Council of the Slovak Republic

Prime Minister of the Government of the Slovak Republic