

Act CLIV of 1997 on Health *

Parliament,

- inspired by its responsibility for the population's health status,
- guided by the conviction that the interest of the individual in his health and well-being must take priority, and that the achievements of the development of medical science should be utilized to ensure positive benefit for present and future generations;
- being aware that health as a prerequisite for the individual's quality of life and self-realization has a major impact upon the family, work and, as a result, the entire nation;
- in consideration of the fact that the system of means and resources available to health services cannot serve the promotion, maintenance and restoration of health unless completed by a social welfare system, the protection of the natural and man-made environment, together with the social and economic environment, as well as by health promoting public policies and practices;
- with regard to recent scientific, technical, ethical, and social changes as well as to amendments and changes affecting the legal system, furthermore to our international obligations,

hereby creates the following Act setting out the complex system of conditions for the promotion and improvement of health.

Chapter I

PURPOSE, FUNDAMENTAL PRINCIPLES AND SCOPE OF THE ACT

Title 1

Purpose of the Act

Section 1

The purpose of this Act is to

- a) foster the improvement of health of the individual, and thereby, of the population, by determining the system of conditions and means influencing health, as well as the responsibilities of those involved in the establishment thereof,
- b) contribute to ensuring equal access to health care services for all members of society,
- c) create the conditions whereby all patients may preserve their human dignity and identity, and their right of self-determination and all other rights may remain unimpaired,
- d) define the general professional requirements and guarantees of quality of health services, regardless of the legal status of service providers and the funding of services,
- e) ensure the protection of health workers and healthcare institutions by defining their rights and obligations, and through safeguards arising from the peculiar nature of health services,
- f) enable that individual and community interests may be asserted in harmony, current public health objectives may be attained, the required funding may be available and deployed in an optimal way, and health sciences may continue to develop.

* Promulgated on 23 December 1997.

Title 2

Fundamental Principles

Section 2

- (1) In the course of delivering healthcare services and measures, the rights of patients shall be protected. A patient's personal freedom and right of self-determination shall be restricted exclusively in cases and in a manner justified by his health status and defined in this Act.
- (2) It shall be required to enforce equity throughout the utilization of healthcare services.
- (3) The primary means of improving health are to promote health and to prevent disease.
- (4) The set of fundamental professional requirements within the healthcare services shall not depend upon forms of ownership and operation, and shall be based exclusively upon the professional contents of the service.
- (5) Structured by levels of care and focussing on man, the healthcare delivery system shall be designed so as to meet the needs as defined by the health status of individuals suffering from diseases of different types and severity; furthermore, it shall be based on evidences and cost-effective procedures.

Title 3

Definitions of Terms

Section 3

For the purposes of this Act:

- a) *patient*: a person using or receiving healthcare services;
- b)¹ *attending physician*: a physician who determines the diagnosis and treatment plan to respond to the patient's illness or health condition, furthermore, a physician or physicians performing procedures and interventions in the frame of such plans who are held responsible for the medical treatment of the patient;
- c) *health care*: a set of healthcare services delivered in connection with the patient's health status;
- d)² *health care worker*: a medical doctor, a dental surgeon, a pharmacist, a person with higher level professional qualification, a person with professional qualification, furthermore a person without qualification involved in delivering health services;
- e)² *healthcare service*: all activities which aim to deliver examination, treatment, continuous care, nursing care and medical rehabilitation, to alleviate pain and suffering, furthermore to perform the work-up of findings from the patient's investigations, in the interest of promoting health; preventing, detecting early and treating disease; managing life-threatening conditions; improving a condition arising as a result of a disease or preventing further deterioration of health; included shall be all activities related to medicines, therapeutic appliances and balneology as provided for by separate pieces of legislation; as well as ambulance and patient transportation services, obstetrical care, special procedures of human reproduction, sterilization, medical research involving human subjects; furthermore all activities related to

¹ Established by Section 1, Subsection (1), Act LXXI of 1999. Effective as of 1 August 1999

² Established by Section 1, Subsection (2), Act LXXI of 1999. Effective as of 1 August 1999

coroner's inquest, medical procedures concerning the dead and transportation of the dead as provided for by a separate piece of legislation;

f) *healthcare provider*: regardless of the ownership form and the maintaining entity, a legal entity, unincorporated organization, or a natural person delivering services in his own right, that are entitled to provide healthcare services on the basis of a license issued by the health authority;

g) *healthcare facility*: a healthcare provider with legal entity as well as an unincorporated healthcare provider delivering specialist inpatient care;

h) *health authority*: the competent office of the National Public Health and Medical Officers' Services (hereinafter referred to as 'NPHMOS');

i) *medical emergency*: a sudden change in health which, in the absence of urgent medical care, would endanger the patient's life, or result in a severe or permanent health impairment;

j) *critical condition*: a condition in which the lack of immediate action would result in a situation directly threatening the life, physical integrity or health of the patient or another person, or a condition which would pose a direct threat to the environment;

k) *examination*: an activity which aims to assess the patient's health status, to promote his health, to detect illnesses and the risks thereof, to diagnose specific disease(s), to establish the likely outcome and any changes of such disease(s), and to establish the effectiveness of medical treatment, as well as the onset and cause of death;

l) *intervention*: any physical, chemical, biological or psychological act performed to for preventive, diagnostic, therapeutic, rehabilitation or other purposes which will, or may, result in a change in the patient's body; furthermore, any procedure related to examinations performed on a corpse and the removal of tissues and organs;

m) *invasive intervention*: a physical intervention penetrating into the patient's body through the skin, mucous membrane or an orifice, excluding interventions which pose negligible risks to the patient from a professional point of view;

n) *life-saving intervention*: a healthcare service aimed at saving the patient's life in case of emergency;

o) *life-supporting intervention*: a healthcare service aimed at maintaining the patient's life in an artificial way or at substituting certain vital functions;

p) *health and medical records*: notes, records or data recorded in any other way, regardless of the carrier or form thereof, that contain medical and personal identification information related to the treatment of a patient and that will come to the knowledge of a health care worker in the course of delivering healthcare services;

q) *professional qualification*: record of professional education or training undergone in Hungary, or undergone abroad and naturalized or recognized in Hungary authorizing its holder to engage in the practice of a profession, such qualification having been obtained in basic, post-basic or higher-level vocational education, in basic education at university or college level, furthermore in the course of specialized professional education of a high level for university or college graduate health care workers;

r) *next of kin*: spouse, direct-line relative, adopted, step and foster child, adoptive, step and foster parents, sibling, and common-law spouse;

s) *Hungarian citizen*: a person holding Hungarian citizenship, or a non-Hungarian citizen who holds a residence permit issued by the competent authority and valid in the territory of the Republic of Hungary, or a person qualifying as a refugee under a separate piece of legislation.

Title 4**Scope of the Act****Section 4**

- (1) The scope of this Act shall extend to
 - a) natural persons residing,
 - b) health care service providers operating,
 - c) healthcare activities pursuedin the territory of the Republic of Hungary.
- (2) Rules deviating from the provisions of this Act may be established by law in respect of specific groups of natural persons.
- (3) Unless otherwise provided by a piece of legislation, the provisions of this Act shall also be applied, as appropriate, to healthcare services delivered by social welfare institutions providing personal care.

CHAPTER II**RIGHTS AND OBLIGATIONS OF PATIENTS****Title 1****The Role of the Individual****Section 5**

- (1) Society's obligations related to health care, together with the individual's responsibility for his own health and that of his environment, ensure the protection and promotion of the population's health.
- (2) Each individual shall respect the rights of others to the promotion and protection of their health, and to the prevention of disease and restoration of health.
- (3) Each individual shall
 - a) have the right to acquire knowledge empowering him to be informed about the possibilities related to the promotion and improvement of his health, and to make informed decisions regarding matters of health,
 - b) have the right to be informed of the features of healthcare services delivered by the healthcare providers, on the accessibility and order of use of such services, as well as on the scope and assertion of the rights of patients,
 - c) assume reasonable responsibility for his own health,
 - d) be obliged to abstain from all behaviors and activities that are commonly known to endanger others' health beyond a socially acceptable level of risk,
 - e) be obliged to provide help, as could be expected of him, and to notify a healthcare provider that he believes is competent if he identifies, or becomes aware of, an emergency or critical condition.

Title 2

Rights and Obligations of Patients

Right to Health Care

Section 6

Each patient shall have a right to receive, in an emergency, life-saving care, care to prevent serious or permanent impairment to health, as well as to have his pain controlled and his suffering relieved.

Section 7

- (1) Each patient shall have a right, within the frameworks provided for by law, to appropriate and continuously accessible health care justified by his health condition, without any discrimination.
- (2) Healthcare shall be considered appropriate if delivered in compliance with the professional and ethical rules, and practice guidelines relating to the specific healthcare service.
- (3) Healthcare shall be considered to be continuously accessible if the operation of the health care delivery is such as to enable its use 24 hours a day.
- (4) Healthcare shall be considered free from discrimination if, in the course of delivering healthcare services, patients are not discriminated against on grounds of their social status, political views, origin, nationality, religion, gender, sexual preferences, age, marital status, physical or mental disability, qualification or on any other grounds not related to their state of health.

Section 8

- (1) The patient shall have a right to choose his attending physician, with the agreement of the healthcare provider of the level justified by his condition and, unless a legal rule sets forth an exception, the physician so chosen, provided it is not precluded by the professional contents of the health service justified by his condition, by the urgency of care or the legal relationship serving as the basis for the use of the service.
- (2)³ The right to choose a physician as in Subsection (1) may be exercised in accordance with the rules of operation of the healthcare provider.
- (3) A patient may initiate that he be examined by a second physician in connection with any diagnosis made or therapy recommended by his attending physician, or regarding his planned discharge from an in-patient institution or referral to another healthcare provider.

Section 9

- (1) If a patient cannot be given the necessary care warranted by his health condition within the shortest possible period of time, the healthcare provider shall be obliged to inform him of the healthcare provider where the specific healthcare service is available.
- (2) The patient shall be placed on a waiting list, if⁴

³ Established by Section 2, Act LXXI of 1999. Effective as of 1 August 1999.

- a) the specific healthcare service cannot be delivered by another healthcare provider, or
 - b) in the case defined in Subsection (1), the patient refuses to be cared for by another healthcare provider.
- (3) If placed on a waiting list, the patient shall be informed of the reason for, and expected duration of waiting, as well as of its possible consequences.
- (4) The patients' order on, and selection from the waiting list shall be based upon unified, controllable and published professional criteria, in a manner justified by the state of health of patients on the waiting list and without any discrimination. The patients' advocate shall also be entitled to verify compliance with these principles, upon written authorization by the patient.
- (5) The waiting list shall contain the medical and personal identification data of patients waiting to receive the specific healthcare service, as well as the circumstances justifying their selection.

The Right To Human Dignity

Section 10

- (1) The patient's human dignity shall be respected in the course of health care.
- (2) Unless otherwise provided by this Act, only the interventions necessary for the care of the patient may be performed.
- (3) In the course of health care, a patient may be restricted in exercising his rights only for the period of time justified by his state of health, and to the extent and in the way, as provided for by law.
- (4) In the course of health care, the patient's personal freedom may be restricted by physical, chemical, biological or psychological methods or procedures exclusively in case of emergency, or in the interest of protecting the life, physical safety and health of the patient or others. Restriction of the patient may not be of a punitive nature and may only last as long as the cause for which it was ordered exists.
- (5)⁵ The application of restrictive methods or procedures shall be ordered by the patient's attending physician, unless otherwise provided by this Act. Prior to applying such restrictive measures, or if it is not possible, within the shortest possible time after the initiation of their application, the attending physician shall enter the restrictive methods or procedures in the medical record, indicating precisely the reasons for and the duration of application. In the absence of continuous medical supervision, in exceptionally justified cases, a registered specialist nurse may also give temporary order for the restriction. The attending physician shall be informed of the restriction without delay, and shall be required to approve it in writing within sixteen hours. In the absence of such approval, the restriction must be discontinued. If restrictive methods and measures are applied, the patient's condition and physical needs shall be observed regularly, in compliance with professional rules. The observation and the findings shall be entered into the patient's medical records.
- (6) A patient may only be made to wait on grounds and for a duration which are reasonable.
- (7) In the course of health care, for protection of his modesty, the patient's clothing may only be removed for the necessary time and to the professionally justified extent.

⁴ The introductory text was established by Paragraph a), Subsection (3), Section 24, Act LXXI of 1999. Effective as of 1 August 1999.

⁵ Established by Section 3, Act LXXI of 1999. Effective as of 1 August 1999.

The Right to Have Contact

Section 11

- (1) The rights set out in Subsections (2) to (7) may be exercised by the patient subject to the conditions existing in the in-patient institution, while respecting his fellow-patients' rights, and ensuring the undisturbed and smooth delivery of patient care. The detailed rules of the latter shall be defined in the regulations of the in-patient institution, without restricting the content of these rights. The hospital regulations may grant further rights, in addition to those set out in Subsections (2) to (7).
- (2) In the course of his stay in an in-patient facility, the patient shall have a right to keep contact with other persons, either in writing or verbally and to receive visitors. The patient may forbid that the fact of his treatment or any other information related to his treatment be disclosed to other persons. This may only be disregarded in the interest of his care, at the request of his next of kin or a person obliged to care for him.
- (3) A patient in a severe condition shall have a right to have the person designated by him stay with him. For a legally incapable patient, the above person might be designated by a person as defined in Subsections (1) and (2) of Section 16. For the purposes of this subsection, a patient in a severe condition is one who, due to his condition, is physically unable to look after himself, or whose pain cannot be controlled even with the use of medication, or who is in a state of psychological crisis.
- (4) A minor patient shall have a right to have his parent, legal representative, or a person designated by him or by his legal representative stay with him.
- (5) A woman in childbirth shall have a right to designate a person of age to stay with her continuously during labor and delivery, and after delivery, to have her new-born baby placed in the same room with her, provided it is not excluded by the mother's or the new-born baby's health condition.
- (6) The patient shall have a right to keep contact with a representative of the church corresponding to his religious beliefs and to freely engage in acts of worship.
- (7) The patient shall have a right to use his own clothes and personal belongings, unless otherwise provided by law.

The Right to Leave the Healthcare Facility

Section 12

- (1) The patient shall have a right to leave the healthcare facility, unless he threatens the physical safety or health of others by doing so. This right may only be restricted in the cases defined by law.
- (2) The patient shall inform his attending physician of his intention to leave, who shall enter this fact in the patient's medical record.
- (3) If the patient has left the healthcare facility without notification, the attending physician shall enter this fact in the patient's medical record, furthermore, if required by the patient's condition, he shall notify the competent authorities, or the legal representative of a legally incapable patient or a patient with restricted disposing capacity, that the patient has left the healthcare facility.

- (4) The patient or his next of kin shall be informed of his planned discharge from the healthcare facility in advance, possibly at least 24 hours prior to such planned discharge.
- (5) In the case of a legally incapable patient, the right defined in Subsection (1) may be exercised with the agreement of the legal representative.

The Right to Information

Section 13

- (1) The patient shall have a right to complete information provided in an individualized form.
- (2) The patient shall have a right to receive detailed information on:
- a) his state of health, including its medical evaluation,
 - b) the recommended examinations and interventions,
 - c) the possible benefits and risks of performing or not performing the recommended examinations and interventions,
 - d) the planned dates for performing the examinations and interventions,
 - e) his right to decide in respect of the recommended examination or intervention,
 - f) the possible alternative procedures and methods,
 - g) the course of care and the expected outcome,
 - h) additional services, and
 - i) the recommended lifestyle.
- (3) The patient has a right to pose additional questions during information and subsequently.
- (4) The patient shall have a right to be informed of the results or eventual failure, or unexpected outcomes and their reasons, after an examination or intervention has been performed in the course of his care.
- (5) The legally incapable patient or a patient with reduced disposing capacity shall also have a right to information corresponding to his age and mental state.
- (6) The patient shall have a right to know the identity, qualifications and professional status of those directly providing services.
- (7) The conditions necessary for the assertion of the rights to information shall be provided by the agency running the healthcare facility.
- (8) The patient shall have a right to be informed in a way which is comprehensible for him, with regard to his or her age, education, knowledge, state of mind and his wish expressed on the matter. If necessary and if possible, the services of an interpreter or a sign language interpreter shall be supplied for the provision of information.

Section 14

- (1) A patient with full disposing capacity may waive the right of being informed, except in cases when he must be aware of the nature of his illness in order not to endanger the health of others. If an intervention takes place at the patient's initiative and not for therapeutic purposes, such waiver of the right of being informed shall only be valid in writing.
- (2) The patient with full disposing capacity shall have a right to designate a person in writing or in any other credible manner who is to be informed in his stead.

(3) The patient shall have a right to be informed even in cases where his consent is not otherwise a condition for initiating medical care.

The Right to Self-determination

Section 15

- (1) The patient shall have a right to self-determination, which may only be restricted in the cases and in the ways defined by law.
- (2) Within the framework of exercising the right of self-determination, the patient is free to decide whether he wishes to use health care services, and which procedures to consent to or to refuse in the course of using such services, taking into account the restrictions set out in Section 20.
- (3)⁶ The patient shall have a right to be involved in the decisions concerning his examination and treatment. Apart from the exceptions defined in this Act, the performance of any health care procedure shall be subject to the patient's consent thereto granted on the basis of appropriate information, free from deceit, threats and pressure (hereinafter referred to as 'informed consent').
- (4) A patient may give his consent as in Subsection (3) verbally, in writing or through implied behavior, unless otherwise provided by this Act.
- (5) Invasive procedures shall be subject to the patient's written consent, or if the patient is not capable of this, to his declaration made verbally, or in some other way, in the joint presence of two witnesses.
- (6) A patient may, at any time, withdraw his consent given to the performance of a procedure. If, however, the patient withdraws his consent without good cause, he may be obliged to reimburse any justified costs that will have incurred as a result of such withdrawal.

Section 16

- (1) Unless otherwise provided by this Act, a person with full disposing capacity may, in a statement incorporated into a public deed, into a fully conclusive private deed, or, in the case of inability to write, a declaration made in the joint presence of two witnesses,
- a) name the person with full disposing capacity who shall be entitled to exercise the right to consent and refuse in his stead, and who is to be informed in line with Section 13,
 - b) exclude any of the persons defined in Subsection (2) from exercising the right of consent and refusal in his lieu, or from obtaining information, as defined in Section 13, by or without naming a person as in paragraph a).
- (2) If a patient has no, or limited disposing capacity, and there is no person entitled to make a statement on the basis of Paragraph a) Subsection (1), the following persons, in the order indicated below, shall be entitled to exercise the right of consent and refusal within the limits set out in Subsection (4), subject to the provisions of Paragraph b) of Subsection (1):
- a) the patient's legal representative, in the absence thereof
 - b) the following individuals with full disposing capacity and sharing household with the patient:
 - ba) the patient's spouse or common-law spouse, in the absence thereof,
 - bb) the patient's child, in the absence thereof,

⁶ Amended by Paragraph a), Subsection (2), Section 24 of Act LXXI of 1999.

- bc) the patient's parent, in the absence thereof,
 - bd) the patient's sibling, in the absence thereof,
 - be) the patient's grandparent, in the absence thereof,
 - bf) the patient's grandchild;
- c) in the absence of a relative indicated in Paragraph b), the following individuals with full disposing capacity and not sharing household with the patient:
- ca) the patient's child, in the absence thereof,
 - cb) the patient's parent, in the absence thereof,
 - cc) the patient's sibling, in the absence thereof,
 - cd) the patient's grandparent, in the absence thereof,
 - ce) the patient's grandchild.
- (3) In the event of contrary statements made by the individuals qualified in the same line to make statement, the decision that is likely to impact upon the patient's state of health most favorably shall be taken into account.
- (4) The statement of the persons defined in Subsection (2) shall be made exclusively following the provision of information, as in Section 13, and it may refer to giving consent to invasive procedures recommended by the attending physician. However, such a declaration – with the exception of the case defined in Subsection (3) of Section 20– apart from the intervention may not unfavorably affect the patient's state of health, and in particular may not lead to serious or lasting impairment to the health. The patient shall be informed of such statements immediately after he regains his full disposing capacity.
- (5) In making decisions on the health care to be provided, the opinion of a patient with no disposing capacity or with limited disposing capacity shall be taken into account to the extent professionally possible also in cases where the right of consent and refusal is exercised by the person defined in Subsection (2).

Section 17

- (1) The patient's consent shall be assumed to be given if the patient is unable to make a statement of consent as a result of his health condition and
- a) obtaining a declaration from the person defined in Paragraph a) of Subsection (1) of Section 16 would result in delay;
 - b) in the case of invasive interventions, if obtaining a declaration from the person defined in, Paragraph a) of Subsection (1) of Section 16 or Subsection (2) of Section 16 would result in delay and the delayed performance of the intervention would lead to a serious or lasting impairment of the patient's state of health.
- (2) The patient's consent shall not be required if failure to carry out the given intervention or action
- a) would seriously endanger the health or physical safety of others, including also the foetus beyond the 24th week of pregnancy, furthermore
 - b) if the patient's life is in direct danger – also taking into account Sections 20 – 23.

Section 18

(1) If, in the course of an invasive intervention, an extension thereof becomes necessary which was not foreseeable, in the absence of a consent to such extension – with the exception of the case defined in Subsection (2) – it may only be carried out if

- a) warranted by a state of emergency, or
- b) failure to do so would impose a disproportionately serious burden on the patient.

(2) If the extension of the intervention defined in Subsection (1) would lead to the loss of an organ or a part of the body or to the complete loss of the function thereof, in the absence of consent to such extension, the intervention may only be extended if the patient's life is in direct danger or in the case defined in Paragraph b) of Subsection (1).

Section 19

(1) The patient's written consent shall be required to the utilization of any of his cells, cell components, tissues, organs and body parts removed while alive in connection with an intervention for any purpose not related to the patient's provision. The patient's consent shall not be required for the destruction of these materials in the usual manner.

(2)⁷ Within the boundaries of this Act, the patient shall have the right to provide for any interventions regarding his corpse in the event of his death. According to the provisions of this Act, the patient may prohibit the removal of any organ and tissue from his corpse for the purposes of treatment, research or education.

The Right to Refuse Healthcare

Section 20

(1) In consideration of the provisions set out in Subsections (2) – (3) and excepting the cases defined in Subsection (6), a patient with full disposing capacity shall have the right to refuse healthcare, unless its lack would endanger the lives or physical safety of others.

(2) A patient shall be required to refuse the provision of any care, the absence of which would be likely to result in serious or permanent impairment of his health, in a public deed or in a fully conclusive private deed, or in the case of inability to write, in the joint presence of two witnesses. In the latter case, the refusal must be recorded in the patient's medical record and certified with the signatures of the witnesses.

(3) Life-supporting or life-saving interventions may only be refused, thereby allowing the illness to follow its natural course, if the patient suffers from a serious illness which, according to the current state of medical science, will lead to death within a short period of time even with adequate health care, and is incurable. The refusal of life-supporting or life-saving interventions may be made in keeping with the formal requirements set out in subsection (2).

(4) Refusal as defined in Subsection (3) shall only be valid if a committee composed of three physicians has examined the patient and made a unanimous, written statement to the effect that the patient took his or her decision in full cognizance of its consequences, and the conditions defined in Subsection (3) have been satisfied, furthermore if on the third day following such statement by the medical committee the patient declared repeatedly the

⁷ Established by Section 4, Act LXXI of 1999. Effective as of 1 August 1999

intention of refusal in the presence of two witnesses. If the patient does not consent to the examination of the medical committee, his or her statement regarding refusal of medical treatment may not be taken into consideration.

(5) Members of the committee defined in Subsection (5) shall be the patient's attending physician, one board-certified doctor specializing in the field corresponding to the nature of the illness who is not involved in the treatment of the patient, and one board-certified psychiatrist.

(6) A female patient may not refuse a life-supporting or life-saving intervention if she is pregnant and is considered to be able to carry the pregnancy to term.

(7) In the event of refusal as defined in Subsections (2) to (3), an attempt shall be made to identify the reasons underlying the patient's decision through personal interviews and to alter the decision. In the course of this, in addition to the information defined in Section 13, the patient shall be informed once again of the consequences of failure to carry out the intervention.

(8) A patient may withdraw his or her statement regarding refusal at any time and without any restriction upon the form thereof.

Section 21

(1) In the case of a patient with no disposing capacity or with limited disposing capacity, healthcare as defined in Subsection (2) of Section 20 may not be refused.

(2) If in the case of a patient with no disposing capacity or limited disposing capacity, healthcare as in Subsection (3) of Section 20 has been refused, the healthcare provider shall institute proceedings for obtaining the required consent from the court. The attending physician shall be required to deliver all medical care necessitated by the patient's condition until the court passes its final and absolute decision. In the case of a direct threat to life, it shall not be required to obtain a substitute statement by the court for the required interventions to be carried out.

(3) An attending physician, in the interest of satisfying his or her obligation defined in Subsection (2) may use the police force, if necessary.

(4) In the course of the proceedings to substitute the statement defined in Subsection (2), the court shall proceed in out-of-court proceedings, without delay. Such proceedings shall be exempt from charges. Unless it otherwise follows from this Act or from the out-of-court nature of the proceedings, the provisions of Act III of 1952 on Civil Proceedings shall apply, as appropriate.

Section 22

(1) A person with full disposing capacity may refuse in a public deed, for the event of his eventual subsequent incapacity,

- a) certain examinations and interventions defined in Subsection (1) of Section 20,
- b) interventions defined in Subsection (3) of Section 20, and

c) certain life-supporting or life-saving interventions if he has an incurable disease and as a consequence of the disease is unable to care for himself physically or suffers pain that cannot be eased with appropriate therapy.

(2) A person with full disposing capacity may name in a public deed, for the event of his eventual subsequent incapacity, the person with full disposing capacity who shall be entitled to exercise the right defined in Subsection (1) in his stead.

(3) The statement defined in Subsections (1) – (2) shall be valid if a board-certified psychiatrist has confirmed in a medical opinion, given not more than one month earlier, that the person had made the decision in full awareness of its consequences. The statement shall be renewed every two years, and may, at any time, be withdrawn, regardless of the patient's disposing capacity and without formal requirements.

(4) In the case of a declaration of refusal of a medical intervention made by a person with full disposing capacity in keeping with Subsection (2), the committee defined in Subsection (4) of Section 20 shall make a declaration on

- a) whether the conditions set out in Subsection (1) exist, and
- b) whether the person defined in Subsection (2) has made the decision in cognizance of its consequences.

Section 23

(1) An intervention as defined in Subsection (3) of Section 20 may only be terminated or dispensed with if the will of the patient to that effect can be established clearly and convincingly. In case of doubt, the patient's declaration made ulteriorly and personally must be taken into account; in the absence of such declaration, the patient's consent to the life-supporting or life-saving intervention must be assumed.

(2) In the course of refusing healthcare, a patient, or the person defined in Subsection (2) of Section 22 must not be forced by any means to alter his decision. Even in the case of refusal of an intervention set forth in Subsection (3) of Section 20, a patient shall have the right to receive healthcare intended to ease his sufferings and reduce pain.

The Right to Become Acquainted With the Medical Record

Section 24

(1) A patient shall have the right to become acquainted with the data contained in the medical record prepared on him or her, and shall have the right to request information on his or her health care data, with regard to the contents of Section 135.

(2) The health care provider shall dispose of the medical record, while the patient shall dispose of the data contained therein.

(3) The patient shall have the right to

- a) be informed of the management of the data related to the medical treatment,
- b) become acquainted with the health care data relating to him,
- c) gain access to the medical record and to receive copies thereof at his own expense,

d) be given a discharge summary upon discharge from the healthcare institution (Section 137),

e) receive a written summary or abridged opinion of his health data for justified purposes, at his own expense.

(4) A patient shall have the right to initiate completion or correction of the medical record relating to him, that he deems to be inaccurate or incomplete, which shall be entered in the medical record by the attending physician, or by another person handling such data, together with his professional opinion. The erroneous health care data may not be deleted following the entry thereof, and shall be corrected in such a way that the data entered originally can be established.

(5) If the medical record prepared of a patient also contains information concerning another person's right to confidentiality, the right of inspection and other right set forth in subsection (3) may only be exercised in respect of the part thereof relating to the patient.

(6) The right to inspect the medical record of a person with no disposing capacity shall be exercised by a person as defined in Subsections (1) and (2) of Section 16.

(7) In the course of health care delivered for his current condition, a patient shall have the right to give written authorization to a person designated by him to inspect the medical record relating to him and to have copies made thereof.

(8) Following the conclusion of the patient's medical treatment, only the person being authorized by the patient in a fully conclusive private deed shall have the right to inspect the medical record and to have a copy made thereof.

(9)⁸ During a patient's lifetime, or following his death, the spouse, a lineal kin, a sibling or common law spouse shall have the right to become acquainted with the health care data, upon written request, if

a) such health data is required in order to

aa) identify a reason that might influence the life or health of the spouse, a lineal kin, a sibling or common law spouse, or

bb) provide healthcare to the persons set forth in Subparagraph aa); and

b) there are no other ways to become acquainted with such health data or to establish them by inference.

(10)⁹ In the case set forth in Subsection (9), only those health data may be learnt that are directly related to the reason defined in Paragraph a) of Subsection (9). Information on the health data shall be provided by the patient's attending physician, or the director of medical services of the healthcare provider, in keeping with the requirements on the provision of medical information, if necessary, based on consultation with the attending physician of the claimant.

(11)¹⁰ In the case of a patient's death, his legal representative, close relative, or heir shall have the right, upon written request, to become acquainted with health data that is, or may be, related to the cause of death, and data that is related to the medical treatment preceding death, furthermore to inspect the medical record and to be provided by copies thereof, at his own cost.

⁸ Established by Subsection (1), Section 5, Act LXXI of 1999. Effective as of 1 August 1999

⁹ Established by Subsection (1), Section 5, Act LXXI of 1999. Effective as of 1 August 1999

¹⁰ Numbering amended and text established by Section 5, Act LXXI of 1999. Effective as of 1 August 1999.

(12)¹¹ The detailed rules of handling and protecting healthcare and related personal data shall be established by a separate law.

The Right to Professional Secrecy

Section 25

(1) A patient shall have the right to have persons involved in his health care disclose his health care and personal data which they might learn in the course of delivering such care (hereinafter: 'medical secret') to those entitled thereto and to have them handle such data confidentially.

(2) A patient shall have the right to make a statement as to who are to receive information on his illness and the expected outcome thereof and who are to be excluded from becoming partially or fully acquainted with his health care data.

(3) The health care data of the patient concerned shall be disclosed even in the absence of his consent thereto when

- a) ordered by law,
- b) required in order to protect the lives, physical safety and health of others.

(4) Health care data, the lack of which may lead to the deterioration of the patient's state of health may be disclosed to a person in charge of a patient's further nursing and continuing care, without the consent of the patient concerned.

(5) A patient shall have the right to have only those persons present during the course of his examination and medical treatment whose involvement is necessary in delivering such care, furthermore those persons to whose presence he has consented, unless otherwise provided by law.

(6) A patient shall have the right to have his examination and treatment take place under circumstances whereby it cannot be seen or heard by others without his consent, unless this is unavoidable due to an emergency or critical situation.

(7) A patient shall have the right to name the person who may be notified of his admission to an inpatient healthcare institution and the development of his state of health, and he shall have the right to exclude any person therefrom. The inpatient healthcare institution must inform the person named by the patient of his admission and any change in his placement, as well of any significant change in the patient's state of health.

¹¹ Numbering amended by Subsection (1), Section 5, Act LXXI of 1999.

Obligations of the Patient

Section 26

- (1) When using a health care service, the patient shall respect and observe the legal rules relating thereto and the institutional order.
- (2) If allowed by his state of health, a patient shall cooperate with the health care workers involved in his care according to his abilities and knowledge, as follows:
 - a) inform them of all details necessary for a diagnosis, the preparation of an adequate treatment plan and for carrying out the required interventions, in particular, of his history of illnesses, medical treatment, medicinal drug use or use of paramedicines, and his health damaging risk factors,
 - b) inform them of every detail in connection with his illness which may endanger the lives or physical safety of others, in particular, of any communicable diseases, and of illnesses and conditions disqualifying him from pursuing an occupation,
 - c) in the case of communicable diseases set forth in the relevant decree of the Minister of Health, name the persons from whom he may have contracted the communicable disease and whom he may have infected,
 - d) inform them of all former legal statements that he might have made in connection with health care,
 - e) comply with the instructions received from them in connection with the medical treatment,
 - f) observe the house rules of the health care institution,
 - g) make the co-payment as provided for by law,
 - h) show credible proof of his personal data as required by law.

Section 27

- (1) In the course of exercising their rights, the patient and his relatives shall respect the rights of other patients.
- (2) The exercise of the rights of a patient and his relatives may not violate the rights of health care workers stipulated by law.
- (3) The method of exercising patients' rights shall be regulated by the house rules of the institution, within the boundaries of this Act.

Title 3

Enforcement of Patient's Rights

Section 28

The health care service provider must inform the patient, upon admission or prior to the actual delivery of care, depending upon his state of health, of the rights of patients, of the possibilities of enforcing such rights and of the house rules of the institution. This provision

shall be applied, as appropriate, in respect of any other persons entitled to exercise the right of self-determination.

Investigation of the Complaints of Patients

Section 29

- (1) A patient shall have the right to lodge a complaint regarding the health care service provided with the health service provider or the maintaining entity.
- (2) The health service provider or the maintaining entity shall investigate the complaint and shall inform the patient of the findings of the investigation in writing within 10 working days. The exercise of the right to complain shall not affect the patient's right to turn to other agencies in the interest of the investigation of the complaint, as defined in separate legal rules. The service provider shall draw the patient's attention to that circumstance.
- (3) The detailed rules of the investigation of complaints shall be laid down in the internal rules of the health service provider.
- (4) Complaints shall be registered and the documents related to the complaints and the investigation thereof shall be kept for 5 years.

The Patient Advocate

Section 30

- (1) The patient advocate shall represent, in keeping with Subsections (2) to (5), the rights of patients defined in this Act and shall help them become acquainted with, and enforce, these rights.
- (2) Patient advocacy services shall include especially the following:
 - a) assistance to patients with having access to medical records, making comments and asking questions thereon,
 - b) assistance to patients with verbalizing their complaints, and initiating the investigation thereof,
 - c) based upon the patient's written authorization, lodging a complaint with the head of the health care institution or the maintaining entity, furthermore taking actions with the competent authorities in matters related to the patient's medical treatment, and representing the patient in the course of such actions,
 - d) informing, on a regular basis, health care workers of the rules relating to patients' rights and any changes therein, as well as of the enforcement of patients' rights in the health care institution.
- (3) The patient advocate may only proceed in individual cases within the boundaries of the authorization granted by the patient.
- (4) The patient advocate shall draw the attention of the head of the service provider or maintaining entity to any unlawful practice and other shortcomings in connection with the operation of the health service provider that he might have experienced in carrying out his duty, and shall make proposals regarding the termination of such practices and shortcomings.

Should this action prove to be unsuccessful, the patient advocate shall have the right to turn to the competent agency or person.

(5) The patient advocate shall pay special attention to representing patients' rights of those at a disadvantage due to their age, physical or mental disability, health status or social situation.

Section 31

(1) The patient advocate shall have to right, within his competence, and in a way which does not jeopardize the undisturbed delivery of health care services, to:

- a) enter the premises of the health service provider,
- b) have access to the relevant documents,
- c) address questions to health care workers.

(2) The patient advocate shall be bound by professional secrecy concerning the patients and shall handle patients' personal data in compliance with the relevant legal rules.

Section 32

(1) The patient advocate shall operate within the organizational framework of the county (Budapest) institution of the NPHMOS.

(2) The patient advocate may not be in employment relationship with the health service provider which provides health services for the patients to be represented by him.

Section 33

(1) The health service provider shall ensure that patients and their relatives may become acquainted with the identity of the patient advocate(s) and the way in which he(they) can be contacted.

(2) The comments and remarks of the patient advocate shall be investigated, to the merit thereof, by the head of the health service provider within 10 working days, and by the maintaining entity within 30 working days [or, where the maintaining entity is a municipality or municipal assembly, at the next assembly meeting]; any position formulated upon such comments shall be communicated to the patient advocate.

Mediation Council

Section 34

(1) With a view to resolve legal disputes which may arise between a patient and a health service provider in out-of-court proceedings, the parties may jointly initiate the settlement of such legal disputes within the framework of mediation proceedings.

(2) The provisions of a separate Act shall apply to the order of mediation proceedings and the composition of the mediation council.

Chapter III

PUBLIC HEALTH

Section 35

- (1) Public health is an organized activity pursued by all of society, targeted at improving the population's health status through health promotion and disease prevention.
- (2) Within the scope of public health action, scientifically founded biological and natural-social environmental conditions for health shall be defined, as shall methods for promoting health and preventing disease that are effective, accessible and acceptable to the population, as shall the specifics of an institutional system required to carry out said activity.
- (3) Within the framework of public health activity,
 - a) the health status of the population shall be assessed regularly, together with the chemical, physical, psychological, biological, environmental, and social factors that influence it,
 - b) based on the data discerned during the analyses, the risks of health hazards shall be evaluated and public health tasks shall be prioritized,
 - c) methods of prevention and of reducing health hazards shall be elaborated,
 - d) in an effort to address these issues, environmental health programs, health promotion, prevention, treatment, and rehabilitation services shall be set up,
 - e) these services shall be regularly evaluated regarding effectiveness, accessibility and other quality indices.
- (4) Data that had been gained in the course of conducting public health activity shall be relied upon when defining the objectives of healthy public policies, and in support of decision-making.
- (5) The public shall be kept regularly informed on the state of public health, on emerging health problems, on causative factors, on expected consequences, on possibilities and limitations of resolving such problems.

Section 36

- (1) Public health is responsible for monitoring and analyzing the state of public health and its determinants, and as part of this activity
 - a) it shall expose the interactions of the human organism and the natural and built environment (together, hereinafter: environment), the health damaging environmental factors and the environmental risks to health, as well as the mechanism of their impact on the human body;
 - b) it shall define
 - ba) the content of materials in media that come into contact with the human body that do not yet pose a health risk,
 - bb) methods of prevention, and of reducing health-damaging effects,
 - bc) the requirements for healthy living and working conditions;
 - c) threshold values for health risks shall be regularly reviewed, and if necessary, shall be modified;
 - d) health risks shall be assessed and measures shall be taken to reduce them;
 - e) a system for reporting health impairment and illness related to environmental factors shall be elaborated;

- f) there shall be regular monitoring of
 - fa) the condition of environmental factors that come into contact with the human body,
 - fb) the extent to which the built environment and working conditions qualify as satisfactory from the aspect of public health.
- (2) When meeting public health tasks, the various systems conducting monitoring and surveillance activities that are considered important to public health shall cooperate with one another.
- (3) Regular monitoring, information provision, and education shall be the basis for preventing health damaging factors.
- (4) When meeting the tasks set forth in Subsection (1), factors detrimental to human health may be restricted or banned.
- (5) Separate statutes shall provide detailed regulation on the various areas of public health.

Title 1

Health Promotion

Section 37

- (1) The objective of health promotion is to improve the state of health and quality of life, and to protect health.
- (2) The principal ways of protecting health are to prevent disease and injury, and to provide health education.
- (3) Prevention is based on
 - a) identifying and assessing risk factors, disseminating information on them to the public, offering incentives targeted at permanent avoidance of the risk factors,
 - b) reducing, and where possible, eliminating risk factors and environmental hazards,
 - c) increasing resistance of the human body to pathogens and other health hazards,
 - d) early detection of susceptibility to disease, prodromal states, disease and complications,
 - e) proper management of existing chronic diseases or pathological conditions, and prevention of their deterioration,
 - f) timely detection of factors leading to psychological pathologies and provision of continuing mental health care.

Section 38

- (1) The public and higher educational systems, the vocational educational system, and adult education shall be used as a framework for presentations adjusted to age and the nature of the studies, to offer information on
 - a) the natural laws governing the operation of the human body, as well as the interactions of the natural, social, and psychological environment,
 - b) the factors needed to establish healthy nutrition, a healthy way of life, and a healthy environment,
 - c) the factors of personal physical and mental health,
 - d) the role of exercise and sports in health promotion and maintenance,
 - e) methods to prevent the evolvement of stressful situations, to resolve them when they arise and to manage conflicts,

- f) sexual culture and family planning, and the ways of preventing sexually transmitted diseases,
 - g) addictions, the damage they cause, and the ways to prevent them,
 - h) the theory and practice of first aid,
 - i) the conditions and opportunities of accessing healthcare services,
 - j) the ethical issues related to health.
- (2) Health education shall encompass information on, and methods whereby disease and prodromal states may be prevented and detected early. This shall include stressing the opportunities and responsibility of the individual to protect his health.
- (3) Every single healthcare worker is tasked with active participation in health education and therefore, in the training of healthcare workers special attention shall be devoted to training that shall enable them to provide lifestyle counseling.
- (4) The stipulations of Subsection (1) shall be considered when defining the qualification criteria in teacher training.
- (5) Public radio and television shall consider health education when designing its program policy.

Section 39

- (1) Persons and organizations noticing factors or engaged in operations and/or activities that are hazardous to public health shall be mandated to report them under separate statute.
- (2) The information set forth in Subsection (1) shall be made public along with the knowledge needed to prevent damage to health.

Section 40

- (1) In addition to health education, the basic tools of health protection shall be immunizations to prevent communicable diseases, a system of screening for early detection of diseases and prodromal conditions, and education for health conducted within the framework of the healthcare system.
- (2) Areas that have a considerable impact on population health on long term include, in addition to the relevant activities of the family physician, family and women's health care, healthcare for communities of children and adolescents (hereinafter: youth health care), occupational health, healthcare for the elderly, and sports health care.

Protecting the Health of Families and Women

Section 41

The objectives of health protection for families and women are

- a) to promote the optimum biological and psychological conditions under which to have children through care and genetic counseling prior to conception, and care through the reproductive cycle (care of the expectant woman throughout the pregnancy, prenatal care for the fetus, and care of the mother through the postpartum and the nursing period),
- b) to provide information to individuals on family planning, including the hazards of terminating a pregnancy, and on contraceptive methods with which they can plan and promote the conception of children in the desired number and spacing, so that the children are born in as healthy a condition as possible,

- c) to provide complex preventive activity adjusted to the biological specifics of women and required for their added protection, to include health protection during the period of life prior to their becoming biologically able to conceive, the periods between fertility cycles, and the time when they are no longer reproductive.

Youth Health Care

Section 42

- (1) The objective of youth health care is to promote the balanced physical and emotional development of minors. This shall include
- a) health education,
 - b) various age-related screenings,
 - c) provision of mandatory immunizations linked to age, monitoring to ascertain that said immunizations were administered and are effective, and the management of immunization campaigns.
 - d) setting forth healthcare considerations in career counseling,
 - e) physicals prior to schooling, evaluation of fitness for given careers, and the provision of periodic examinations monitoring fitness for a given career in educational facilities that offer vocational training together with academic curricula.
- (2) The special tasks of youth health care shall include
- a) increased monitoring of, and psychological care for youth having congenital defects, chronic diseases, or physical, sensory, or mental disabilities, based on cooperation with family physicians, and to promote adjustment to and integration in healthy communities,
 - b) meeting the healthcare tasks related to school physical education, facilitated or special physical education, and student sports,
 - c) provision of counseling following consultations with parents and teachers, or if necessary, initiating appropriate action upon noticing the existence of circumstances endangering balanced physical and emotional development, use of alcohol or illegal drugs.
- (3) Within the framework of youth health care,
- a) inspection shall cover
 - aa) adherence to public health requirements in facilities engaged in academic education and practical training, as well as in facilities available for outdoor programs and recreation areas,
 - ab) meals served in crèches and educational and training institutions,
 - ac) adherence to epidemiological rules and specifications,
 - ad) ascertainment that first aid provision requirements are being met
 - ae) ascertainment that rules on consumption of alcohol, narcotic drugs and other psychotropic substances, and on tobacco products are adhered to,
 - af) the psychological state of students and the amount of work they can manage;
 - b) the necessary epidemiological measures shall be taken in case of an outbreak of communicable disease;
 - c) first medical treatment shall be provided for children and students in education and training institutions.

(4) School healthcare shall be considered a part of youth health care as set forth under separate statute.

(5) As part of their tasks, primary and specialized healthcare providers shall focus special attention on preventing, detecting, and eliminating factors that are hazardous to the health of children. To do this, they shall cooperate with institutions and individuals involved in education, social welfare, family assistance and child protection, and may initiate all necessary appropriate measures.

Sports Health Care

Section 43

The objectives of sports healthcare are

- a) to provide preliminary medical fitness examinations, and to routinely monitor persons regularly involved in student sports and leisure sports,
 - b) to screen out persons for whom increased physical exertion is hazardous, and to detect latent diseases,
 - c) to monitor the sports health aspects of expertly managed exercise suited to physical condition and exerting a beneficial physiological affect, and to provide counseling on sporting activity and the related lifestyle,
 - d) to offer counseling in managing school physical education, facilitated physical education, and special physical education tasks,
 - e) to monitor sports events, to prevent and provide first medical care for sports injuries, and to take any additional measures necessary,
 - f) to design sports and exercise programs, to investigate their effects, and to monitor them, together with medical rehabilitation specialists when possible.
- (2) Activity pursued by sports physicians for competitive athletes shall be a specialized area of sports healthcare, targeted at determining whether prospective athletes are sufficiently healthy and medically fit to participate in a given sport, and at preventing any possible health consequences of the given sport through periodic check-ups by sports physicians.
- (3) Sports healthcare also shall be responsible for supervising the ban on illegal performance enhancing drugs, other agents, products, and methods, and for conducting related research and counseling, and for preventing use of said substances and methods.

Title 2

Environmental and Settlement Health

Section 44

(1) Adherence to public health specifications shall be mandated and inspected when designing, establishing, re-organizing, using, operating, transforming, renovating and eliminating settlements, buildings, facilities and utilities, when operating equipment, and when manufacturing and using means of transport.

(2) Public and private areas shall be maintained in conformity with public health requirements. The owner or user shall provide for said maintenance.

Section 45

- (1) Environment and settlement health is charged with investigation of the health hazards of environmental factors and with finding the means of preventing them.
- (2) Within the framework of activity as set forth in Section (1), regular investigations shall be conducted on the pollution levels of the soil, of surface and ground waters, of drinking water, and indoor and outdoor air, of the condition of sewage conduits and solid waste placement, and of the health hazards of all of the above, of environmental noise, vibration and light hazards, of hazards caused by temperature and atmospheric pressure, and of the level of ionizing and non-ionizing radiation, and of the health damage caused by same.
- (3) If the level of an environmental factor exceeds health threshold values, the persons within the area affected shall be informed, and the measures needed to prevent damage to health shall be reported at the same time. Measures depending on the nature of the shortcoming shall be taken to eliminate the shortcoming thus disclosed and to prevent health damage.
- (4) As part of environmental and settlement health activity
 - a) the public shall be educated about environmentally polluting activities with which they are endangering their own health and/or the health of others, and about circumstances and factors that pose a hazard to a healthy environment that persons generally can be expected to recognize, as well as about the manner in which they can report them,
 - b) a system for reporting health damage or health impairment related to environmental hazards shall be evolved.

Section 46

Soil, water, and air must not be infected or polluted to the extent that it poses a direct or indirect hazard to human health.

Section 47

- (1) Materials and products that pose a threat to human health (hereinafter: hazardous materials) shall be produced, imported, distributed, transported, stored and used, and residues or waste material from same shall be processed or disposed of in keeping with the requirements and specifications of statutes regulating chemical safety.
- (2) Activity set forth in Section (1) may be bound to prior procurement of a permit from the health authority.
- (3) Mandatory reporting and recording of certain hazardous materials may be ordered to protect human health.
- (4) If health has been damaged, or if there are strong grounds for believing that it has been damaged, the health authority may suspend activity with the hazardous material, or it may ban use of the hazardous material altogether.

Title 3

Food and Nutritional Health

Section 48

Food health shall be tasked with investigating foods for public human consumption (hereinafter: food) including

- a) defining and regularly monitoring the health threshold values of microbiological, chemical and radiation contamination
- b) defining and regularly monitoring the public health requirements for production and distribution,
- c) defining and regularly monitoring the health and hygiene standards for persons involved with production and distribution,
- d) investigating any intoxications and infectious diseases mediated by them, exposing the causes, maintaining records of them, and preventing any further occurrences.

Section 49

- (1) Food only shall be prepared, treated, distributed or imported when the materials used or contained in it, and the manners in which they are used or contained in it are not hazardous to consumer health and meet food health and public health specifications.
- (2) Food shall be produced, processed, packaged and/or distributed with the approval of the health authority as specified under separate statute, and in possession of a permit issued by said authority.
- (3) When producing a food, only those additives, technological ancillary materials, food packaging products, detergents, and disinfectants that have been registered with the responsible health authorities shall be used.
- (4) Only persons whose health does not pose a hazard to consumer health, and who possess the professional, health, and hygienic information required for such activity shall participate in the production, handling, or distribution of food.
- (5) Children's toys intended to be placed in the mouth or usually placed in the mouth, and other objects placed in the mouth when used, including cosmetics, shall be treated as foods when considering conformity to public health standards.

Section 50

- (1) The nutritional health service is charged with conducting investigations on the dietary situation and nutritional status of the public, and on interactions between nutrition and state of health, and on that basis, with elaborating nutritional recommendations.
- (2) Information and education shall be used as tools to acquaint the public with healthy nutrition, and with the healthy way to prepare and handle food, as well as with the modes of avoiding nutrition-related health hazards.
- (3) Public meal services, shall provide food of a quality that meets biological and nutritional requirements.

Title 4 Radiation Hygiene

Section 51

- (1) The objective of radiation safety activity is to protect the health of humans and their progeny from the hazardous effects of ionizing and non-ionizing radiation, during the appropriate use of radiation.
- (2) In the interests of the safe use of radiation, involving risk at a level that is acceptable to society, the radiation hygiene is tasked with:
 - a) discovering the sources of radiation to which humans are subjected, determining the level of said radiation, and monitoring it,
 - b) studying the properties of radiation and its interactions with living matter,
 - c) investigating the effects of radiation on humans through medical observational research, and clinical and epidemiological methods,
 - d) elaborating the rules, and the effective and economic ways and means of protection against the hazardous effects of radiation,
 - e) taking measures and controlling implementation of said measures to design and maintain working and living conditions that are safe from the point of view of radiation hygiene.
- (3) Sources of ionizing radiation only shall be operated when in possession of a permit from the health authority; and radiation health regulation and monitoring measures to be taken in cases of over-exposure, and the conditions for using radioactive materials and disposing and storing radioactive waste shall be in accordance with the requirements and specifications of the Nuclear Energy Act.
- (4) The combined radiation from artificial sources shall not exceed the dose limit value established by the authorities. This limit shall not be applied to persons subjected to radiation from medical diagnostic instruments or through therapy, with the voluntary consent of said persons.

Section 52

- (1) Producing, processing, distributing, transporting, using, collecting and storing radioactive materials and products; processing, transporting and definitively disposing radioactive waste; or manufacturing, using or operating instruments and equipment that emit ionizing radiation shall be done only under a permit issued by the responsible authority.
- (2) Increased radiation exposure or a radiation injury, or any suspicion of contamination by a radioactive material shall be reported to the health authority.
- (3) Areas, materials, and persons contaminated with radioactive materials shall be decontaminated, and the health authority may ban use of contaminated materials, or may order treatment of the contaminated materials, or demolition of the contaminated facility.

Title 5 Workplace Health

Section 53

The objective of workplace health activity is to protect the health of workforce personnel by

- a) foreseeing, detecting, evaluating and treating health hazards and risks within the workplace environment (hereinafter: workplace hygiene), and by
- b) investigating and influencing strain and stress caused by workplace pathogens or resulting from the work process, as well as by evaluating, monitoring and promoting the health of the workforce, which includes determining whether they are healthy and fit enough to do the job (hereinafter: occupational health).

Section 54

Workplace hygiene is charged with

- a) elaborating the threshold values of workplace sanitary conditions at which there is still no risk to health;
- b) elaborating and applying methods to demonstrate the presence of workplace pathogens, and a system of workplace monitoring;
- c) assessing expected health risks of technological development, and of new workplaces while still in the design phase;
- d) assessing health risks on the basis of actual workplace environments, technologies, materials employed, and products, and providing qualitative and quantitative specifications of said risks;
- e) assessing risks following a comparison of values and data actually measured with the corresponding threshold values and standards;
- f) elaborating prevention strategies;
- g)¹² operating through its services to act as an enforcement authority in order to attain the targets of workplace hygiene.

Section 55

Occupational health is charged with

- a) carrying out, based on the data identified by workplace hygiene, analyses of the effects on the workforce of various pathogens in the workplace environment and the human response to these effects, and collecting evidence of the parameters typical of the human reaction;
- b) elaborating procedures suitable for early detection of occupational diseases;
- c) defining the maximum allowable exertion for a worker while working;
- d) determining the amount of work a person is able to handle through medical examinations to determine whether the given worker is fit to work in the given position or occupation, and to define the conditions under which he may be employed;
- e) determining the frequency with which the medical fitness examinations are to take place, on the basis of knowledge of the workplace environment and the nature of the job itself;
- f) qualifying a worker as fit or unfit to do a given job, and determining the type of work environment and the conditions under which the person is fit to work;
- g) paying increased attention to monitoring the health of working minors, women, pregnant women, nursing mothers, elderly people, people with chronic diseases, and people with disabilities;

¹² Amended by Paragraph b), Subsection (3), Section 24, Act LXXI of 1999.

- h) initiating the occupational rehabilitation of persons with changed ability to work, or participating in said rehabilitation.

Title 6

Epidemiology

Section 56

- (1) The objective of epidemiology is to prevent and control the spread of infectious diseases and epidemics, and to increase human resistance to infectious diseases.
- (2) To implement the objective set forth in Subsection (1)
- a) the health authority
 - aa) may limit the rights of individuals to exercise personal liberties as set forth in this Act,
 - ab) may limit the rights of patients as set forth in this Act,
 - ac) may mandate natural and legal entities as well as unincorporated entities to tolerate or take the measures defined in this Act;
 - b) the health service taking mandatory epidemic management measures may limit the rights of patients as set forth in this Act.
- (3) When taking mandatory epidemiological measures, the consent of patients is not required, but patients shall continue to be entitled to the right to receive information, as appropriate to the circumstances of their cases.
- (4) When applying Sections 57-74, the concept of a person with an infectious disease shall also include persons who are suspected of having an infectious disease.

Immunizations

Section 57

- (1) The objective of immunization is to provide an active or passive immunity to infectious diseases.
- (2) The Minister of Health shall issue a decree setting forth the infectious diseases for which mandatory immunizations may be ordered
- a) as a function of age,
 - b) when there is a risk of contracting a disease or
 - c) when traveling abroad, in which case the traveler shall cover the immunization costs.¹³
- (3) As a prerequisite for employment in certain occupations the Minister of Health may mandate immunization, the costs of which shall be covered by the employer.¹³
- (4) A person not mandated to receive an immunization may be inoculated at his own request, or with the agreement of a legal guardian in the case of a minor, in medically justified cases.
- (5) Treatment with prophylactic medication administered to prevent the outbreak of certain infectious diseases shall be considered equivalent to immunization.
- (6) Immunization only shall be given with a vaccine authorized by the health authority, and only for the purpose and under the conditions specified in the permit.

¹³ Cf. Decree 18/1998 (VI.3.)NM

(7) Decrees set forth under separate statute shall regulate the production, placing on the market, and administrative inspection of vaccines and other immunobiological preparations.

Section 58

(1) An attending physician may transitionally, or, with the approval of the health authority, permanently exempt a patient from a mandatory immunization if said person's health is expected to be damaged, or an existing disease exacerbated, by the immunization.

(2) Records shall be kept of persons mandated to receive immunizations, and of persons receiving them.

(3) Persons mandated to receive immunizations, or legal guardians of said persons shall be notified of the manner, purpose, venue, and time of the immunization. When a minor is mandated to receive an immunization, the legal guardian shall be responsible for ensuring such minor's attendance.

(4) If a person mandated to receive an immunization does not appear despite a written request to do so, the health authority may issue a decision ordering that the immunization be given. The decision may be executed immediately, even if legal remedy is sought.

(5) A certification of receipt of an immunization shall be given.

(6) A person who has received immunization can be ordered to undergo a medical examination and to provide a specimen to determine the effectiveness of the immunization.

(7) Should a person mandated to receive an immunization suffer injuries or death in association with receipt of the immunization, the person or his dependants shall receive compensation from the state.

Screenings for Epidemiological Considerations

Section 59

(1) The objective of screening for epidemiological considerations is to detect the presence of infectious diseases in an early phase, to track down the sources, and to avert the danger of contagion.

(2) The Minister of Health shall issue a decree setting forth the infectious diseases for which the health authority may order the mandatory screening of

- a) the entire population,
- b) specific population groups,
- c) the residents of a specific area,
- d) all people at a workplace, in a family, or in another community,
- e) persons arriving from other countries,
- f) persons in contact with one of more infected persons

to prevent contagion.¹⁴

(3) A Minister of Health Decree may provide for the mandatory screening for epidemiological considerations as a prerequisite for employment in specific jobs, or for the donation of blood, organ or tissue for transplantation.¹⁴

¹⁴ Cf. Decree 18/1998 (VI.3.)NM

Section 60

- (1) Persons mandated to participate in screening, or legal guardians of said persons shall be notified of the manner, purpose, venue, and time of the screening examination. When a minor is mandated to participate in a screening, the legal guardian shall be responsible for ensuring such minor's attendance.
- (2) If a person mandated to appear for screening does not appear despite a written request to do so, the health authority may issue a decision ordering that the screening be conducted. The decision may be executed immediately, even if legal remedy is sought.
- (3) When screening is ordered for epidemiological considerations, it shall include the time necessary to travel to and from the screening venue and shall qualify as a mandatory medical examination with respect to application of labor statutes.

Notification of Infectious Diseases

Section 61

- (1)¹⁵ Persons with infectious diseases and persons suspected of having infectious diseases shall be notified to the registry of persons with infectious diseases, in keeping with the stipulations of Subsection (2).
- (2) Rules for notifying and registering infectious diseases, and for handling related data shall be set forth in a separate Act.

Mandatory Medical Examination

Section 62

- (1) Any person noticing symptoms of an infectious disease on his own person or on that of a person under his care is mandated to initiate a medical examination.
- (2) Any person ordered to appear for a medical examination by a physician because of a suspected infectious disease is mandated to
 - a) to appear for said examination, or if unable to appear for an examination because of the illness, to submit to said examination at his place of residence,
 - b) to provide samples for necessary laboratory examinations or to make collection of said samples possible;
 - c) to subject himself to treatment including preventive drug treatment,
 - d) to comply with medical instructions.

Isolation

Section 63

- (1) The physician detecting the disease shall take measures to isolate the infectious patient, in a manner set forth under Subsection (2), for the period of communicability.

¹⁵ Established by Section 6, Act LXXI of 1999. In force as of 1 August 1999

(2) A person suffering from an infectious disease as defined in the Minister of Health Decree shall be isolated in his home, place of residence, or in a separate ward for infectious diseases in an inpatient facility or designated healthcare institution. People suffering from certain infectious diseases as specified in the Minister of Health Decree shall be isolated and treated exclusively in a ward for infectious diseases in an inpatient facility or designated healthcare institution.¹⁶

Section 64

- (1) An infectious patient may be isolated in his home or place of residence if
 - a) the condition of the patient makes this feasible,
 - b) isolation conditions can be provided, and
 - c) the patient or legal guardian agrees to adhere to epidemiological regulations for the duration of the isolation.
- (2) When isolated in an inpatient facility, the right of an infectious patient to freedom of movement within the facility and the right to maintain contacts with others may be restricted.
- (3) Should an infectious patient within an inpatient facility be non-compliant with isolation requirements, the health authority may issue a decree mandating compliance. The decree mandating compliance with isolation restrictions may be executed immediately, even if legal remedy is sought.

Epidemiological Observation and Quarantine

Section 65

- (1) A person who has been in contact with someone suffering from a infectious disease and who is assumed to be in the incubation period for said disease may be placed under epidemic observation or quarantine for infectious diseases set forth in the appropriate Minister of Health Decree.¹⁶
- (2) A decision taken by the health authority in keeping with Subsection (1) may be executed immediately, even if legal remedy is sought.

Section 66

- (1) During the period in which a person has been placed under epidemiological observation, he may be restricted in pursuing his occupation, his right to maintain contacts, and in his right to freedom of movement.
- (2) During a period of epidemiological observation, the provisions of Subsection (2) of Section 62 shall be applied as appropriate.
- (3) Epidemiological observation shall be concluded within 48 hours after the expiration of the average incubation period for the given infectious disease if medical examination/testing precludes the possibility of contagion.

Section 67

- (1) Quarantine is defined as observation or isolation based on tightened and special requirements, that shall occur at a venue stipulated for such purposes.

¹⁶ Cf. Decree 18/1998. (VI.3.)NM

(2) Subsection (1) of Section 66 shall be applied for persons placed in quarantine, noting that the person placed in quarantine may not leave the place where the quarantine was ordered.

Epidemiological Surveillance

Section 68

(1) A person carrying a pathogen for a infectious disease set forth in the Minister of Health Decree, and excreting said pathogen without himself being in any stage of the infectious disease itself, is considered to be a pathogen carrier.¹⁷

(2) The health authority may place a pathogen carrier under epidemiological surveillance for the duration of the period in which he is a carrier.

(3) Placing a pathogen carrier under epidemiological surveillance shall be mandatory for infectious diseases set forth in the Minister of Health Decree.¹⁷

(4) A decision by the health authority under Subsections (2) and (3) may be executed immediately, even if legal remedy is sought.

Section 69

(1) A pathogen carrier placed under epidemiological surveillance may be restricted in pursuing his occupation, his right to maintain contacts, and in his right to freedom of movement, depending on the manner in which contagion occurs.

(2) If medical examinations/tests determine that maintenance of epidemiological surveillance is not justified, it shall be terminated.

(3) Depending upon the nature of the infectious disease, a pathogen carrier shall

a) be mandated to subject himself to periodic medical examinations/tests, to provide samples to be tested or to allow such samples to be taken,

b) be mandated to report to the health authority in advance of leaving his home for a period of time exceeding two weeks which shall include reporting the new place of domicile,

c) not remove any food or equivalent product from his home or household for public consumption,

d) not enter any childcare or educational institution,

e) not work in any occupation involving child protection, education, healthcare or welfare, or food production, processing, packaging, or distribution or the drinking water supply,

f) be mandated to comply precisely with health regulations.

Section 70

During periods of epidemiological isolation, epidemiological observation, and quarantine, as well as during epidemiological surveillance, the necessary and justified costs of implementation which arose through no fault of the infectious patient or the pathogen carrier, and the equivalent of lost income which is not reimbursable through the social insurance system, shall be reimbursed to the infectious patient or the pathogen carrier by the state.

¹⁷ Cf. Decree 18/1998 (VI.3.) NM

Transport of Infectious Patients

Section 71

- (1) An infectious patient may be transported by a patient-transportation vehicle. The vehicle used to transport the patient shall be disinfected when the disease is one that is set forth in the Minister of Health Decree.¹⁸
- (2) If the infectious patient cannot be transported as set forth in Subsection (1), or if the patient was unaware of the contagion and traveled to seek medical assistance using his own vehicle or a vehicle belonging to someone else, but not public transport, this same vehicle may be used to transport the patient to a final destination. In this case, when necessary, disinfection of the vehicle and persons accompanying the patient may be ordered [Subsection (3) of Section 72].
- (3) In exceptional cases an infectious patient may be transported by a public transport vehicle, in which case the vehicle shall be properly disinfected.

Disinfection

Section 72

- (1) During the period of contagion, if justified by the nature of the disease, the attending physician shall take measures to continuously disinfect the place of residence of the infectious patient, and to disinfect, or if necessary, to destroy objects used by the patient, clothing, and body fluids.
- (2) After the patient is no longer infectious, or the infectious patient is transported elsewhere, or dies, a terminal disinfection of the place where the patient was treated and if necessary, of the surrounding area, shall be conducted. The health authority shall order said terminal disinfection at the initiative of the attending physician. The decree of the health authority ordering the terminal disinfection may be executed immediately, even if legal remedy is sought.
- (3) If necessary, persons involved with the care of the infectious patient, with handling infectious materials and objects, with transport of the infectious person or with the disinfection, shall undergo personal disinfection. The persons involved are mandated to cooperate with the disinfection and to tolerate the disinfection process.
- (4) The health authority shall provide the disinfection agents needed for the terminal disinfection.

Extermination of Insects, Other Arthropods, and Rodents

Section 73

- (1) Owners and managers of areas and/or buildings shall take regular measures to exterminate insects and rodents set forth under separate statute, that transfer infective agents or diseases or are otherwise detrimental to the health. Users of the areas or buildings are mandated to tolerate the extermination.

¹⁸ Cf. Decree 18/1998 (VI.3.) NM

(2) A person with parasitic arthropods on his body surface or epidermis is mandated to tolerate their extermination and the disinfection of his clothing.

Miscellaneous Epidemiological Measures

Section 74

(1) The health authority shall determine an epidemic hazard or the presence of an epidemic (together, hereinafter: an epidemic).

(2) In case of an epidemic

a) the operation of all institutions, programs or activities that can promote the spread of the epidemic,

b) travel by persons, or the transport of live animals or commodities from one region to another,

c) personal contacts between persons in one region and persons in another region,

d) visiting at healthcare facilities,

e) leaving certain areas

f) the sale and consumption of certain foods,

g) the consumption of drinking water and

h) the keeping of certain livestock

may be restricted or prohibited.

(3) A decree by the health authority in accordance with Subsection (2) may be executed immediately, even if legal remedy is sought.

Chapter IV

THE HEALTHCARE SYSTEM

Title 1

Principles of Operation

Section 75

- (1) The healthcare system makes it possible to provide healthcare services in a manner coordinated with the implementation of public health objectives.
- (2) The objectives of healthcare services are to contribute to the maintenance of individual health, to restoration of health to the extent possible, to reducing the deterioration of health, and to promote the integration of persons with altered health into work and into the community.
- (3) The healthcare system is built upon a system of institutions that is intended to provide differentiated care to persons in differing states of health and is based on the principle of division of labor and progression, in which the combination of all specific features that make up the state of health of an individual shall determine the level of care necessary (hereinafter: progressive healthcare).
- (4) Within the healthcare system, available resources shall be used efficiently to improve the overall state of public health.

Section 76

- (1) The principle of progressive healthcare shall be valid for all levels of healthcare.
- (2) The personnel and objective conditions necessary to provide the various healthcare services within progressive healthcare shall be defined under separate statute.

Section 77

- (1) When a patient presents in what is suspected of being an urgent or emergency situation, the patient shall be examined irrespectively of whether or not said patient is legally entitled to use the facility, and if the examination certifies the need for urgent or emergency care, said patient shall receive the emergency care required by the state of his health.
- (2) Entitlement to using emergency care shall be determined only after the patient is examined and treated. Should the patient not be entitled to the given care free of charge, procedure for the ex post payment of fees shall be in accordance with those set forth under separate statute.
- (3) All patients, irrespective of entitlement to using healthcare services, shall be treated by all care providers with maximum care, in adherence of professional and ethnical rules and guidelines.

Section 78

- (1) In the event that the healthcare provider is unable to provide the care required by the condition of the patient, once any necessary emergency care has been provided, the patient shall be transferred to a service provider which has the facilities necessary to complete patient care.

(2) After providing care for the patient, the referring physician shall be notified, or if there was no referral, notification shall go to the family physician. If the referring physician is someone other than the patient's family physician and the state of patient's health requires long-term continuous care, the family practitioner shall be notified in addition to the referring physician.

(3) If, in medical opinion, the patient is seeking to access health services exceeding those justified by his state of health, use of said services may be restricted or made to depend on conditions by statute, depending on the legal relation underlying the use of healthcare service.

Title 2 Preventive Services

Section 79

Healthcare provision to prevent diseases or to diagnose them in an early phase (hereinafter: preventive services) is tasked with

- a) increasing or, if necessary, establishing resistance to infectious diseases
- b) conducting screenings to detect various diseases and prodromal conditions, with particular respect to
 - ba) family and women's health,
 - bb) preventive dental care,
 - bc) mental health, involving both prevention and continuing care,
 - bd) healthcare for children and adolescents,
 - be) detection of significantly hazardous infectious diseases,
 - bf) early diagnosis of diseases significant from the aspect of public health,
 - bg) conducting screenings linked to age;
- c) early detection of possible damage to health caused by the individual's living or working conditions;
- d) determining medical fitness for participating in certain activities, as defined by statute;
- e) completing examinations/tests aimed at early diagnosis of other diseases that are unrelated to the specific episode of care;
- f) completing examinations/tests for early detection of any expected consequences or complications of an illness for which a patient is being treated;
- g) taking measures to eliminate abnormalities or pathologies detected when conducting the measures under Paragraphs a) - f).

Prevention of Infectious Diseases

Section 80

Prevention of infectious diseases is based on

- a) immunization and other types of treatment focused on prevention,
- b) screenings conducted for epidemiological considerations,
- c) fulfillment of general epidemiological tasks,

- d) use of personal protective devices, and
- e) evolving and shaping a general health-conscious attitude.

Screenings

Section 81

- (1) The purpose of screenings is to protect the health of the public, and improve the individual's quality of life and to increase lifespan, by active detection and diagnosis of latent diseases, of the prodromal state of certain diseases, and of risk factors making a person susceptible to diseases, preferably before they cause patient complaints.
- (2) Screenings conducted in mass numbers of the population of certain ages, or related to infectious diseases, or certain chronic non-communicable diseases, shall be conducted when all of the following conditions exist:
 - a) the disease to be screened for occurs frequently or seriously damages the health, and it can be diagnosed before the onset of complaints through screening.
 - b) the screening is likely to be successful, and is easy to do,
 - c) conditions for effective therapy following the screening are available.
- (3) Within screenings linked to age, the screening of neonates and children upon reaching school age is mandatory for the cases set forth by statute. When a minor is mandated to participate in a screening, the legal guardian shall be responsible for the appearance of the minor. If legal guardian does not respond despite a written request to do so, the health authority may issue , even if legal remedy is sought.
- (4) Above and beyond the stipulations set forth in Subsection (3), statutes can offer incentives to participate in screenings; and can sanction non-participation by withdrawing benefits, if doing so does not have a detrimental influence on health.

Section 82

- (1) Early detection of diseases and prodromal states shall occur through routine screenings linked to other types of care (hereinafter: routine screening), or through targeted screening.
- (2) Screening conducted in the course of providing other care and aimed at early detection of age-related diseases, as set forth under separate statute, shall be qualified as routine. The attending physician shall be mandated to call the need for age-related screening to the attention of the given patient or the patient's legal guardian, and
 - a) to complete the screening within his sphere of competence or
 - b) to refer the individual to a healthcare provider authorized to carry out the screening.
- (3) Screening is targeted when it is focused on screening specific at-risk segments of the population based on age, gender or certain risk factors, or when it is aimed at detection of certain endemic diseases of public health importance.
- (4) The attention of the groups in question shall be called to the targeted screening in a comprehensible manner that is accessible to all, and shall include the precise object, date, time, and venue of the screening. If the screening is organized for a group that is at risk because of some environmental factor, the persons involved shall also be individually notified of the object, date and time, and venue of the screening.

Prevention Based on Individual Risk Factors

Section 83

(1) In order to prevent health damage that may occur because of individual living conditions, in settlements where environmental factors can become health risks, public health activity shall ascertain the risk factors, eliminate them, regularly monitor them and eliminate their consequences.

(2) If, when providing healthcare to the residents of a settlement, it is noticed that certain diseases are more prevalent than anticipated, the health authority shall be notified immediately for it to conduct the activities listed in Subsection (1), giving them high priority. If the investigation concludes that there are environmental factors in the given area that can lead to the development of diseases, the health authority shall initiate immediate action to eliminate the risk factors.

(3) Simultaneously with the measures in Subsection (2), the population of the area shall be screened to detect the specific health damage, and measures shall be taken to eliminate the pathogenic source and provide care to persons who have been affected.

Section 84

(1) The means of preventing possible health damage resulting from the individual's working conditions:

- a) investigating and monitoring workplaces (including the places where work is done outside of the framework of organized work) from the point of view of occupational health,
- b) enforcing measures intended to protect the health of people working there,
- c) investigating to determine whether or not a worker is fit to handle the given job without endangering his own health or the health of others, and without any foreseeable physical injury.

(2) When conducting preliminary and interim examinations to determine whether a worker is fit for a job and to recognize any deterioration in health stemming from working conditions in an early phase, special attention shall be focused on

- a) detecting prodromal states,
- b) recognizing a tendency towards health impairment stemming from working conditions,
- c) conducting screenings focused on detecting occupational disorders as set forth by separate statute.

Section 85

The objective of medical fitness examination concerning the pursue of an activity that does not qualify as work, both before beginning said activity and routinely repeated while it is being conducted, is to determine whether or not a person is fit to do the activity without a threat to his own or others' health and physical well-being.

Monitoring Healthy Fetal Development and Protecting the Health of Expecting Mothers

Section 86

(1) Monitoring healthy fetal development, prevention or early detection of risks and complications, and preparations for delivery, breast-feeding and infant care shall take place within the framework of protection of families and women.

(2) In the course of prenatal care of expectant mothers, provided within the framework of protection of families and women, the health of the expectant woman, as well as her family, social, and workplace circumstances shall be monitored, and the examinations/tests set forth under separate statute to monitor the health of mother and fetus shall be completed.

Title 3

The Healthcare Delivery System

Section 87

(1) The healthcare delivery system shall provide healthcare to patients on an outpatient basis, within an inpatient facility, and in their homes.

(2) The healthcare delivery system shall operate in keeping with needs assessed in the course of public health activity.

(3) Expansion of the healthcare delivery system and improvement of its standards shall take place in coordination with socio-economic resources.

Primary Health Care

Section 88

(1) All patients shall be assured continuous long-term healthcare based on a freely chosen personal relationship, in or near their places of residence, irrespective of gender, age or the nature of their illness.

(2) The objective of the primary health care set forth in Subsection (1) is

a) to provide the preventive services to the public served, as set forth under Section 79;

b) with respect to the individual patient:

ba) to monitor his state of health, and to provide health information and education,

bb) to treat, care for, and provide rehabilitation for him, within the framework of competencies set forth under separate statute, with a given diagnostic and therapeutic back-up,

bc) to refer him to specialists for diagnosis of an illness, preparation of a treatment plan, or therapy,

bd) to treat him, and to provide home nursing and rehabilitation on the basis of a treatment plan recommended by the attending physician;

c) when necessary, to provide the services as in Sub-Paragraphs bb) and bd) within the patient's home, and to call for a specialist consultation to be held in the patients home.

Outpatient Specialized Care

Section 89

- (1) General outpatient specialized care shall be understood as one-off or occasional health care provided on a referral from the physician regularly attending and caring for a patient, or on the self-referral of the patient, or continuous specialist care when the patient has a chronic condition not necessitating inpatient care. General outpatient specialized care shall be provided at a venue accessible through public transport without endangering the health of the patient (hereinafter: close to where the patient lives).
- (2) The care set forth in Subsection (1) shall include
- a) preventive measures,
 - b) medical treatment and specialist care of the individual patient, which shall include making provisions for skilled nursing care at home and rehabilitation,
 - c) specialist consultations, including consultations in the patient's home if necessary,
 - d) in the event that special medical, diagnostic or therapeutic backup is necessary, referral of the patient, following examination, to another outpatient specialized facility or specialized ambulatory clinic,
 - e) a one-time intervention or a course of treatment for the patient within the competency of specialized outpatient care, which requires subsequent monitoring for specific periods of time,
 - f) referral of the patient to an inpatient facility should the patient require an institutional hinterland.

Section 90

- (1) In addition to the general outpatient specialized care set forth under Section 89, specialized outpatient care with enhanced diagnostic and therapeutic backup services shall be provided for a predefined number of population as determined, under separate statute, by the incidence of diseases (hereinafter: enhanced outpatient specialized care).
- (2) Enhanced outpatient specialized care shall be understood as healthcare organized to treat diseases that require special knowledge and expertise, or special financial, physical and professional conditions.

Inpatient Specialized Care

Section 91

- (1) General inpatient specialized care shall be understood as healthcare provided in an inpatient facility close to where the patient lives. The patient shall access said facility, as set forth under separate statute, through a referral by the physician providing the patient with regular care, by an attending physician or other authorized person, or by the self-referral of the patient himself.
- (2) Care, as set forth under Subsection (1) may consist of
- a) diagnosis, treatment, rehabilitation or nursing, provided to a patient who has been admitted as an inpatient, including long-term care,
 - b) care, with the objective set forth in Paragraph a), provided at specified times of day,
 - c) singular interventions or a course of treatment which requires subsequent monitoring for a specific period of time, and which guarantees further immediate healthcare, if necessary, during the monitoring period.

Section 92

- (1) In addition to the level of care set forth under Section 91, enhanced inpatient specialized care with enhanced diagnostic and therapeutic backup and the ability to resolve medically complex tasks shall be provided for a predefined number of population as determined under separate statute by the incidence of diseases.
- (2) Patients may access the enhanced inpatient specialized care as set forth under Subsection (1) through a referral by
- a) the physician providing specialist outpatient care or providing specialist care within an inpatient facility,
 - b) if urgent need exists, by the physician responsible for providing in-area care, or by a physician or paramedic serving on an ambulance,
 - c) by a family physician, when the medical conditions for enhanced specialist care are present.

Title 4

Miscellaneous Healthcare Services

On-Duty Services

Section 93

- (1) The on-duty service is to continuously provide the healthcare services set forth under Sections 88-92 for emergency cases occurring at times other than during the usual workday.
- (2) The objective of the on-duty service is to provide patient examinations, to observe the patient's health, to carry out one-time and immediate emergency interventions, to urgently refer patients to inpatient facilities, and to participate in procedures set forth under separate statute from the time healthcare services conclude one working day until the time they begin the following working day.

Ambulance Service

Section 94

- (1)¹⁹ Ambulance service shall be understood as emergency care delivered by an organization authorized to provide emergency services for a patient in need of immediate health care at the site where he is located, and in connection with this , when necessary, to transfer the patient to the nearest healthcare provider able to provide the care required by patient's condition, and to provide care to the patient while en route (hereinafter: ambulance service).
- (2) A patient shall require immediate healthcare services
- a) in cases of accidents involving personal injury, mass accidents, or disasters,
 - b) if the patient is in or is suspected of being in a life-threatening condition,

¹⁹ Amended by Paragraph c), Subsection (3), Section 24 of Act LXXI of 1999.

- c) if the patient displays acute or alarming symptoms, and/or if the absence of emergency care may lead to a life-threatening condition, permanent health damage, or to prolonged recovery,
 - d) in the course of an obstetrical event,
 - e) if relief from major pain or another serious acute system requires urgent medical intervention,
 - f) if the patient is in an acute confusional state,
 - g) if a condition endangering health exists or is suspected.
- (3) In the cases set forth under Subsection (2) anyone is authorized to call the ambulance services.
- (4) Other procedures qualifying as ambulance service include
- a) Urgent transport (immediate and within one hour) ordered by a physician, or transport under watch requiring stand-by ambulance service irrespective of the urgency,
 - b) transport of a physician or medical team to conduct a life-saving activity as defined under other statutes (e.g., for organ transplants),
 - c)²⁰ urgent transport of life-saving medical appliance and pharmaceuticals or of an organ for transplant,
 - d) a mobile ambulance watch (provision of stand-by ambulance services in a specified time and place).

Section 95

The right to access the ambulance service is open to everyone within the borders of the Republic of Hungary, irrespective of nationality, or health insurance coverage.

Section 96

- (1) Provision and organization of the system needed for safe, uniform and coordinated ambulance services shall be a central government task.
- (2) Ambulance services throughout the country shall be provided by the National Ambulance and Emergency Service (hereinafter: NAES) and other organizations authorized to provide ambulance services, as defined in their license, under the coordination of the NAES.

Patient Transport

Section 97

- (1) The objective of patient transport as ordered by a physician, is to ensure access to healthcare in cases when access to healthcare cannot otherwise be ensured, particularly if the patient
 - a) only may be transported in a certain position;
 - b) requires supervision during transport because of the illness;
 - c) has a mobility impairment, is unable to ambulate, or has a medical condition that precludes use of the usual means of transport;
 - d) may not use public transport because of a contagion hazard, or pathological behavior;

²⁰ Established by Section 7 of Act LXXI of 1999. In force as of 1 August 1999.

e) the delay resulting from use of the usual means of transport would put the success of treatment at risk.

(2) In addition to the conditions set forth in Subsection (1) a patient discharged from a healthcare institution may be transported to his home if

a) the patient is unable to leave the institution for any of the reasons set forth under Subsection (1), Paragraphs a) - c), or

b) if no means of public transport is available to the patient at the given time.

(3) A helpless intoxicated person in a public area or public place shall be transported by the ambulance and emergency service to a detoxifying facility. The person may be detained at the detoxifying facility until he becomes sober, limited to a maximum of 24 hours in duration.

Nursing

Section 98

(1) Nursing qualifies as the total of nursing and caregiving procedures targeted at improving the patient's health, at maintaining and restoring health, at stabilizing the patient's condition, at preventing illness, at alleviating suffering while maintaining the human dignity of the patient, and at preparing the patient's environment to participate in nursing tasks and including them in said tasks.

(2) Nursing

a) is aimed at assisting a patient in conducting activities which he cannot do alone or only can do with significant difficulty because of his medical condition, or which would result in a deterioration of patient's condition, or which require special training,

b) is aimed at restoring patient's ability to care for himself, to reduce the pain of an illness and to alleviate suffering;

c) serves to assess the responses to and needs of actual or possible health problems,

d) serves to carry out the interventions called for in the therapeutic plan ordered by the attending physician,

e) is tasked with providing health education and counseling services.

(3) Nursing shall be

a) an integral part of healthcare services provided to a patient in an institutional setting,

b) a supplementary part of therapy and rehabilitation provided to a patient in his home,

c) a fundamental element of nursing and caregiving provided to a patient in an institutional setting or in his home.

(4) Nursing and caregiving based on a nursing care plan shall assist the patient in conducting the activities that contribute to his health, recovery, or rehabilitation. In the cases set forth under Paragraphs a) and b) of Subsection (3), considering the interactions of medical diagnosis and therapy, the nursing care plan shall be approved by the physician attending the patient. In the case set forth under Paragraph c) of Subsection (3), the nurse shall prepare the nursing care plan on his own, and shall implement it independently.

(5) Nursing and caregiving shall be documented in nursing documentation, which shall form a part of the healthcare documentation

End-of-Life Care of Terminal Patients

Section 99

- (1) The objective of end-of-life care of terminal patients (hereinafter: hospice care) is to provide physical and emotional nursing and care for a patient with a lengthy terminal illness, to improve his quality of life, to alleviate suffering, and to preserve the patient's human dignity all the way to the end of life.
- (2) To achieve the objective set forth under Subsection (1), the patient is entitled to palliative care to mitigate pain, alleviate physical symptoms and emotional suffering, and to have family members and other significant persons at his side.
- (3) Whenever possible, hospice care shall be provided in the patient's home, with patient surrounded by his family.
- (4) Hospice care shall include assisting family members of the terminal patient in nursing the patient, and providing emotional support to them for the duration of the illness and during the period of bereavement and mourning.

Rehabilitation

Section 100

- (1) Rehabilitation is organized assistance provided by society to persons with disabilities resulting from transitional or permanent damage to their health, or physical or intellectual abilities, to promote their reintegration into the community by making use of their restored or remaining abilities.
- (2) Rehabilitation involves the application of healthcare, psychological, educational, occupational, and welfare measures in a planned, combined and coordinated manner tailor-made to the individual, and with the active participation of the involved person.
- (3) Habilitation is a rehabilitation-type activity focused on a child or possibly an adult whose development has been arrested by a congenital or developmental disorder, illness or accident, and who is therefore hindered in participating in community life.
- (4) The objective of medical rehabilitation is to develop the existing abilities, or find substitutes for the abilities, of persons whose health has been damaged or who have disabilities, through the tools of health science, to assist in the fullest possible restoration of their independence, so that they become able to adjust to family, workplace and other communities.
- (5) Integral parts of medical rehabilitation are, in particular, physical therapy, sports therapy, speech therapy, psychological care, occupational therapy, and the provision of therapeutic appliances and teaching patients how to use them.
- (6) Therapeutic appliances shall serve patients to retain their fundamental life functions, and establish substitutes for functions that have been lost, and shall thus improve patient autonomy, quality of life, and ability to work.

Medical Devices Supply

Section 101²¹

Medical devices, including therapeutic appliances, may be put on the market and used in healthcare if

- a) they satisfy the qualify specifications set forth under separate statute and have been issued the certifications and specification documents set forth in the statute, and
- b) if the organization set forth under separate statute has registered them.

Supply of Pharmaceuticals**Section 102**

The supply of pharmaceuticals is an integral part of healthcare services, and is targeted at providing proper quality, safe, effective and cost efficient pharmaceuticals that are listed in the official pharmaceutical register, and as set forth under separate statute, for preventive and curative activities.

Psychotherapy and Specialized Clinical Psychology**Section 103**

- (1) Psychotherapy is a therapeutic process based on a variety of scientifically-founded methods, used to treat persons with psychological or psychosomatic disorders in multiple therapeutic sessions, each with a set time-frame, which may be provided for individuals or groups by a physician or a graduate psychologist having the required qualification.
- (2) Specialized clinical psychology shall be applied to
 - a) retain and restore psychological well-being,
 - b) diagnose, examine and discern the causes of psychological disorders,
 - c) conduct the psycho-diagnostic tests required to diagnose certain disorders, and
 - d) apply psychological methods to correct psychological disorders.
- (3) Psychotherapy shall require the completely voluntary participation of both patient and therapist.
- (4) A medical examination shall be necessary prior to the initiation of psychotherapy. In the course of his work, a specialized clinical psychologist shall be obliged to obtain medical consultations in all cases when this is justified by the condition of the patient, or by the need to protect the condition of the patient.
- (5) A physician psychotherapist is authorized to provide a combination of pharmaceutical treatment and psychotherapy.

²¹ Established by Section 8 of Act LXXI of 1999. In force as of 1 August 1999.

Non-conventional Procedures²²

Section 104

(1) Non-conventional therapeutic and complementary procedures (together, hereinafter: non-conventional procedures) are aimed at favorably influencing the state of health, preventing illness or making it possible to build defenses against factors endangering or damaging the health.

(2)²³ Non-conventional procedures are based on methods that differ in their outlook toward health and illness, and apply a different approach than conventional procedures founded on the natural sciences, and, as set forth under separate statute, are procedures that are complementary to, or in predefined cases, substitute for conventional therapeutic methods. Non-conventional procedures that substitute for conventional therapy shall only be applied under the supervision of a physician.

(3)²⁴ A separate statute shall define the scope of non-conventional procedures and the prerequisites for engaging in the practice of the individual activities.

(4)²⁴ The contents of Chapters II and VI shall be appropriately applied with respect to patient rights, obligations to provide information and documentation, and to the rights and obligations of the service providers, when non-conventional procedures are used.

Other therapeutic services

Section 105

Supplementary healthcare services, which are an integral part of therapy when ordered by a physician, but which also may be accessed without physician's orders, within the framework of the professional rules governing provision of a given healthcare service, are also a part of healthcare.

Expert Services within the Healthcare Framework

Section 106

Healthcare services include services provided by medical experts within the framework of preventive-curative services, and in relation to claims of benefits under the social insurance scheme, particularly the rendering of decisions or opinions of health with regard to

- a) whether or not a person's health renders him fit to perform a particular job or to work in a particular occupation,
- b) ability to pursue gainful activity,
- c) the level of a disability, and the level and quality of the remaining ability to work and/or the conditions under which a person may continue to work.

²² Title amended by Paragraph b), Subsection (2), Section 24 of Act LXXI of 1999.

²³ Amended by Paragraph b), Subsection (2), Section 24 of Act LXXI of 1999.

²⁴ Amended by Paragraph b), Subsection (2), Section 24 of Act LXXI of 1999.

Chapter V

PROFESSIONAL REQUIREMENTS OF HEALTHCARE SERVICES

Section 107

The objective of the system of professional requirements of healthcare services is to guarantee

- a) a satisfactory quality of healthcare services, with particular respect to their effectiveness and efficiency, and
- b) the rights of recipients and providers of healthcare services.

Title 1

Conditions for Beginning and Providing Healthcare Services

Section 108

- (1) Healthcare services shall be begun and provided only in possession of a license of operation issued by the health authority, and only in accordance with the conditions set forth in the license.
- (2) A license of operation shall be issued only if the applicant has liability insurance to cover any damages caused while providing healthcare services. If the liability insurance is terminated the insurer is mandated to immediately report said termination to the authority issuing the license, which shall revoke said license unless the healthcare provider has obtained liability insurance from another insurer.
- (3) The service provider is mandated to immediately report any change in the conditions necessary for operation to the health authority.
- (4) The health authority shall regularly monitor the existence of conditions necessary for operation.

Title 2

System of Objective Conditions

Section 109

The system of objective conditions at the health service provider shall meet the requirements necessary to provide care, and shall meet the specifications set forth as conditions of operation.

Title 3

System of Personnel Conditions

Section 110

(1) Healthcare activity, with the exception of the cases set forth in Subsections (2) and (4), shall be conducted by a person who has the professional qualifications that authorize for practicing said activity or who has professional qualifications attainable without healthcare training, and who is listed in the operations registry.

(2) Healthcare activity restricted to professional qualifications, above and beyond the conditions set forth in Subsection (1), only shall be conducted by a person with proper professional qualification. A person participating in training to gain the specialist professional qualifications, or a person possessing the specialized qualifications and deleted from the registry as set forth in Paragraph a) or Paragraphs c) - g) of Subsection (1) of Section 113 shall be permitted to conduct this type of work under the supervision of a person with the proper specialist qualifications in the interests of eliminating the reason for the deletion, and until such time as the reason for the deletion has been eliminated, and said person shall be returned to the operations registry.

(3) Activity conducted independently as set forth in Subsections (1) - (2) may begin after registration of the specialized professional qualifications in the operations registry.

(4)²⁵The Executive Office of the Chief Medical Officer (hereinafter: EOCMO) of the health authority may, in justified cases, issue a permit to engage in a specific activity corresponding to qualifications limited in duration and in venue (to a workplace) to a person possessing the said specialized professional qualifications, not listed in the operations registry, in keeping with the procedural order set forth under separate statute.

(5) A person who does not possess the specialized healthcare qualifications to provide healthcare services also may participate in the provision of said services under the supervision and in keeping with the instructions of a person who meets the conditions set forth in Subsection (1). The right of the supervisor to issue instructions shall be limited to the scope of said supervisor's professional competence.

(6) The person set forth under Subsection (5), who participates in the provision of healthcare services in a sphere that does not correspond to his professional qualifications, shall begin and conduct said activity only following prior and appropriate education.

(7) The provisions of Subsections (5) - (6) shall not apply to persons who possess the professional qualifications authorizing them to conduct healthcare activity without specialized healthcare training.

(8) In keeping with the provisions set forth under Subsections (1) - (7) a person not otherwise authorized to provide healthcare services may participate in the provision of healthcare services to herself/himself, or in the medical treatment of any other person who has agreed to this, in keeping with the provisions of Section 15. The sphere of such participation shall be defined by the nature of the intervention and/or illness, the professional qualifications and skills of the person participating, and the instructions of the attending physician.

²⁵ Amended by Paragraph d), Subsection (3), Section 24 of Act LXXI of 1999.

(9) A healthcare worker who is acting as supervisor shall not be responsible for damage to health resulting from activity conducted by a person as set forth in Subsection (8), unless said damage was caused by

- a) improper instructions by the healthcare worker,
- b) neglect or improper fulfillment of the supervision obligation,
- c) a breach of the obligation to educate or prepare the persons set forth in Subsection (8) which can be considered the fault of the healthcare worker.

Basic Registration of Persons with Healthcare Qualifications

Section 111

(1) All persons possessing healthcare qualifications attained at a recognized educational institution within Hungary, or attained in another country and recognized or naturalized in Hungary, shall be entered in the basic registry after procurement of the degree or certificate.

(2) The objective of the basic registry is to attest to the authenticity of the professional qualifications attained.

(3) The basic registry shall contain the following data:

- a) the name, maiden name, place and date of birth, mother's maiden name, and citizenship of the person who has earned the qualifications;
- b) stipulation of the specific qualifications earned, the number of the degree or certificate attesting to this, the place and date of issue, and the name of the institution which issued it.

(4) The data set forth in Subsection (3) shall be reported to the basic registry by the educational institutions issuing, recognizing or naturalizing the degree or certificate within 30 days following said issuance, recognition or naturalization.

(5) The Ministry of Health shall maintain the basic registry in accordance with the levels of qualification.

Operational Registry of Healthcare Workers

Section 112

(1) On request, all persons who meet the conditions set forth in this statute shall be entered into the operational registry.

(2) The objective of the operational registry is to attest to the data of healthcare workers as set forth in Subsection (4).

(3) A person shall not be entered in the operational registry if said person

- a) is not listed in the basic registry,
- b) refuses to provide the data set forth under Paragraph a) of Subsection (4),
- c) is unable to credibly certify proper continuing education and practical experience that is due and a prerequisite to conducting any healthcare activity in any healthcare profession, and/or having successfully taken a profession-focused language test in specified cases,
- d) in case he was registered should be deleted from the registry in keeping with Paragraphs b) - d) of Subsection (1) of Section 113,
- e) has been deleted from the operational registry in keeping with Paragraphs e) or g) of Subsection (1) of Section 113, for a period of one year following the deletion,

- f) has been deleted from the operational registry in keeping with Paragraph f) of Subsection (1) of Section 113, until certification of completion of the continuing education.
- (4) The operational registry shall contain the following data:
- a) name, maiden name, place and date of birth, mother's maiden name, home address (place or residence), citizenship of the healthcare worker;
 - b) the type of professional qualification, specialist qualification earned, the number of the degree or certificate attesting to this , the place and date of issue, and the name of the institution which issued it;
 - c) the date(s) of completion of continuing education required by statute;
 - d) the number, date and place of issue, and name of the body issuing a certificate of language skills;
 - e) limited fitness to work [Subsection (1) of Section 114];
 - f) place of work;
 - g) clinical placement period(s), duration of interruptions in healthcare activities exceeding one year;
 - h) scientific degrees.
- (5) The healthcare worker is mandated to report changes in data set forth in Subsection (4) and in Paragraphs a) - f) of Subsection (4)- with the exception of Subsection (6) -within 30 days of said changes occurring.
- (6) The Council of Professional Qualification and Continuing Education in Health shall ex officio notify the body maintaining the operational registry of persons passing professional examinations, and of completion of continuing education as set forth in Paragraph c) of Subsection (4).
- (7) The operational registry shall be maintained by the professional chamber corresponding to the level of qualifications, or in lieu of such a chamber, by the Ministry of Health.
- (8) The names of healthcare workers set forth in Paragraphs b) - f) of Subsection (4), and Paragraph a) shall qualify as data registered in the public interest.
- (9) A healthcare worker shall be registered in the , on request of the person appearing in the registry.
- (10) The body maintaining the operations registry shall renew the registration - unless there is cause for excluding said registration from the registry.

Section 113

- (1) The body maintaining the operational registry shall delete a person from the registry, while simultaneously notifying the employer of the healthcare worker and the health authority, if
- a) said person has not renewed the registration,
 - b) said person is subject to a legally binding court decision setting forth an executable sentence of incarceration exceeding one year or banning pursuit of occupation,
 - c) said person has a health condition, because of which the health authority has qualified said person to be permanently unfit to conduct healthcare activity,
 - d) said person's insight has been reduced and he has been banned from practicing healthcare activity by the health authority for this reason,
 - e) said person has deliberately provided false data on registration to the body maintaining the operational registry,

- f) said person has failed to certify completion or beginning of due continuing education as set forth under Paragraph c) of Subsection (3) of Section 112 within 30 days of the due date,
 - g) said person begins conducting an activity bound to a prerequisite of specialized training without or prior to reporting completion of the appropriate training or specialized training to the operations registry, unless otherwise specified by statute,
 - h) said person is deceased,
 - i) said person's membership in the chamber is terminated, if mandatory membership in a chamber is specified by law.
- (2) In the case of Paragraph b) of Subsection (1) the court, and in the case of Paragraphs c) - d) the body determining the unfitness shall notify the body maintaining the operational registry.
- (3) The death of a registered person shall be reported to the body set forth in Subsection (1) by the healthcare provider or by the body issuing the operation permit.

Unfitness to Conduct Healthcare Activity

Section 114

- (1)²⁶ Healthcare activity shall be conducted only by a person authorized as a healthcare worker, whose state of health and insight deems him able and fit to conduct the given activity.
- (2) A healthcare worker, who for reasons of health, becomes permanently unable to conduct healthcare activity, or becomes permanently limited in conducting such activity, shall be deemed unfit to conduct said activity by the health authority, or fit to conduct healthcare activity only under limited conditions. When a person is found fit to conduct healthcare activity only under limited conditions, the health authority shall define the healthcare activities that can be conducted. If the health of the healthcare worker undergoes a significant change, the worker may request that the health authority find him fit.
- (3) When the insight of a healthcare worker has been reduced and he has become unfit to conduct healthcare activity for that reason, the health authority can ban him from conducting activity for the duration of the unfitness. The health authority shall revisit the condition of the healthcare worker who has been banned at least once every other year.
- (4) When a student in an educational institution providing healthcare training becomes unfit to conduct healthcare activity for a reason set forth under Subsection (2), the person shall be suspended from continuing his studies for the duration of the unfitness.
- (5) The health authority shall consider the opinion of an occupational health specialist physician or of the National Institute of Medical Expertise when determining unfitness or limited fitness in keeping with Subsection (2), or a forensic specialist psychiatrist when determining unfitness in keeping with Subsection (3).
- (6) Detailed rules on bans and suspensions shall be set forth under separate statute.

²⁶ Established by Section 9 of Act LXXI of 1999. In force as of 1 August 1999.

Basic, Post-Basic and Continuing Education in Health

Section 115

- (1) The role of basic education in health is to train professionals whose knowledge, abilities, and skills render them able to properly conduct the healthcare tasks for which they have been trained.
- (2) The role of post-basic education in health is to provide the theoretical knowledge and practical professional skills that corresponds to the degree and level of training.
- (3) The role of continuing education is to maintain and advance the level of knowledge and skills already possessed, in keeping with the current level of science and the requirements of healthcare provision.
- (4) Healthcare workers who have obtained basic qualification at the college level may attend college or university level continuing education or specialization courses.
- (5) Healthcare workers who have obtained basic qualification at the university level (physicians, dentists, pharmacists) may participate in higher educational professional training to gain the specialized theoretical knowledge and practical experience for specific professions set forth in the Minister of Health Decree within the framework of legal employment (hereinafter: higher level professional education in health) through which they shall earn higher level qualifications as specialist physicians, specialist dentists, or specialist pharmacists.

Section 116

- (1) Professional education in health shall take place within the framework of basic, mid-level, and higher level professional education, and on university and college level, in keeping with statutes on vocational training and higher education.
- (2) The rules governing the education (higher level specialist education) and continuing education of specialist physicians, specialist dentists, specialist pharmacists, and specialist clinical psychologists, including the specialized healthcare education and continuing education of persons with other higher educational degrees, shall be set forth by the Minister of Health in a decree coordinated with the professional chambers.²⁷
- (3) Education and continuing education in health shall take place in educational institutions and in the facilities of health service providers which have the personnel and material conditions to provide said training.²⁸

Section 117

- (1) The Council of Professional Qualification and Continuing Education in Health (hereinafter: CPQCEH) shall serve as the body preparing decisions, and providing recommendations and proposals to the Minister of Health regarding basic, post-basic and continuing education in health, higher level specialist training and higher level continuing education, and shall meet the tasks set forth under Subsection (2), and in the Minister of Health Decree.
- (2) The CPQCEH shall

²⁷ Cf. Decree 73/1999. (XII.25.)Eü.M.

²⁸ Cf. Government Decree 125/1999 (VIII.6.) Korm.

- a) provide opinions on all draft statutes affecting professional and continuing education in health;
 - b) provide opinions on the overall number of students and the numbers in each specialization who shall be financed by the state when attending university or college level basic healthcare training;
 - c) participate in defining the professional conditions, uniform principles and programs of specialist physician, specialist pharmacist, and specialist dentist training and continuing education for healthcare workers, and shall qualify and coordinate said principles and programs on a nationwide scale,
 - d) meet the tasks of higher level professional specialist training as set forth under separate statute.
- (3) In keeping with the Minister of Health Decree, representation of
- a) the institutes of higher education participating in basic and post-basic education,
 - b) the institution coordinating the basic, mid-level, and higher level professional training of healthcare workers,
 - c) the professional chambers operating in healthcare, or in lieu of such, of the representative professional organizations affected,
 - d) the professional colleges,
- within the CPQCEH shall be ensured.
- (4) One representative of the Ministry of Education, and of the Ministry of Social and Family Affairs shall be invited to participate in the work of the CPQCEH.

Section 118

- (1) Persons working in healthcare shall have the right to participate in professional education, specialist professional training and in continuing education. Statutes may mandate continuing education and may simultaneously define the conditions for participation in said continuing education.
- (2) In order to ensure the professional level of healthcare provision, the Minister of Health shall participate in setting the training requirements for university and college level basic training.
- (3) The Minister of Health shall set the conditions and requirements for the various basic, mid-level, and higher levels of professional training, and for higher level specialist training.

Title 4

Ensuring the Quality of Healthcare Services

The Quality System

Section 119

- (1) The objective of the quality system is to assure the quality of healthcare services.
- (2) In order to meet the objective set forth in Subsection (1), the quality system shall include the definition of quality requirements, and the monitoring and evaluation, and when necessary, certification of their fulfillment, as well as continuous quality improvement.

- (3) Fundamental conditions of appropriate quality of healthcare services shall be that
- a) these services be delivered only by providers in possession of the personnel and material conditions set forth by statute;
 - b) the rules set forth by statute or other professional rules be enforced in the course of care provision, in particular, the operation of professional guidelines reflecting the current position of science and based on evidence, or in lieu of this , of rules set forth in methodological guidelines, or in lieu of professional standards or methodological guidelines, of the professional requirements published in widely accepted professional literature;
 - c) these services offer the individual
 - ca) treatment resulting in the greatest possible real improvement in his state of health,
 - cb) the opportunity for exercising patients' rights;
 - d) these services be provided in a professionally effective way, using available resources in an optimum manner.

Section 120

The quality and quality improvement of healthcare services shall be assured through the quality assurance, quality development, and monitoring systems of the healthcare provider (hereinafter: internal quality management system), and through the quality assurance, quality improvement and monitoring systems, and the certification of compliance of the organization exercising professional supervision (hereinafter: external quality system).

The Internal Quality Management System

Section 121

Each healthcare institution shall provide for the operation of its own internal quality management system, the objective of which shall be

- a) to continuously improve the quality of service, and to become acquainted with and plan the details of the service provision process, which shall include the planning of ways to prevent possible errors,
- b) to quickly detect shortcomings in service provision, to take the measures needed to eliminate them, and to monitor implementation,
- c) to discover the causes of shortcomings, and to reduce related costs and damage,
- d) to meet professional and quality standards, and to develop the specific system of internal standards.

The External Quality System

Section 122

The external quality system shall operate on the basis of the operational order under which operation licenses are provided to healthcare services and shall proceed to define, publish and regularly monitor

- a) the requirements necessary for the provision of services,
- b) the professional content of the various services,
- c) the criteria applied in evaluating services,

d) the quality standards of the documentation system and provision of data on the procedures applied,
as well as to supervise the compliance of healthcare providers and services and to provide certification of compliance.

Professional Supervision

Section 123

- (1) The health authority shall exercise professional supervision over healthcare providers and services.
- (2) As part of its professional supervision, the health authority shall monitor adherence to health sector statutes and professional rules.

Certification of Compliance

Section 124

- (1) Certification of compliance shall involve supervising and certifying the quality of the healthcare service's quality system and the services provided by given provider.
- (2) Healthcare providers may initiate certification when desiring recognition of compliance for voluntarily provided services that improve the quality of care and expand the professional content.
- (3) The organization authorized to certify compliance shall certify compliance as set forth in Subsection (2) - for the period of time set forth under separate statute - by issuing a certificate of said compliance.
- (4) Only the healthcare provider in question may make public the certificate of compliance and/or its content.
- (5) During the validity of the certificate of compliance, the organization authorized to provide certification may conduct periodic surveys. Should conditions disclosed during the periodic surveys not meet the ones for which the certificate was issued, the certificate may be invalidated. In this case, the provisions of Subsection (7) shall be properly applied.
- (6) A healthcare provider with a certificate of compliance may initiate repeated certification prior to the expiration of the validity of said certificate. Should the re-investigation find that the service provider is not meeting the conditions that existed at the time the certificate of compliance was issued, the organization authorized to re-issue the certificate of compliance shall deny re-issuance.
- (7) When the validity of the certificate of compliance that has been made public expires, if the certificate of compliance is not re-issued, the service provider shall inform involved parties of this in the manner defined by the Minister of Health Decree.

Chapter VI

RIGHTS AND OBLIGATIONS OF HEALTHCARE WORKERS

Care Provision Obligation of Healthcare Workers

Section 125

In emergencies, irrespective of time and place, the healthcare worker shall provide first aid to any person in need, to the extent that said healthcare worker can provide such aid under given conditions with the implements available, and/or shall immediately take necessary measures. In cases of doubt, the existence of an emergency shall be presumed.

Section 126

(1) When mandated to provide in-area care, the healthcare worker shall take the measures during his working hours, as set forth in Subsections (2) and (5) and in keeping with the professional competencies and expertise of the healthcare worker, to provide care for a patient requesting it.

(2) A physician, assuming that he is authorized to do so on the basis of professional competence and expertise, shall examine all patients requesting to be seen. Depending on the findings of the examination, he shall treat the patient or, in the absence of proper objective and personnel conditions, shall refer the patient to a physician or healthcare provider with the proper conditions.

(3) Examination of the patient shall include investigating all complaints of which the attending physician is aware, ascertaining patient's medical history and discovery of individual circumstances that influence patient recovery.

(4) The measures set forth in Subsections (2) - (3) shall be circumvented only in cases when life-saving interventions of pressing necessity are required.

(5) A healthcare worker who does not have medical qualifications shall provide such examinations for patients requesting them that are within his competency, or when they exceed the healthcare worker's scope of competency, he shall notify a physician with the authority to conduct said examinations. In this latter case, however, if made necessary by patient's condition, until arrival of the physician, he shall complete all interventions for which he is authorized on the basis of professional competency and experience.

Section 127

(1)²⁹ For the duration of the time a physician is absent or otherwise prevented from providing care,

- a) the employer of the attending physician
- b) in lieu of an employer, the attending physician himself
- c) or if the attending physician is prevented from providing care, the regionally responsible health authority, at the expense of the healthcare provider,

²⁹ Established by Section 10, Act LXXI of 1999. In force as of 1 August 1999.

shall have to arrange for the examination and treatment of the patient through another physician, which shall not include the situation when there is an on-duty physician handling the work of the attending physician.

(2) The physician requested to attend to the patient as a substitute, or the on-duty physician, shall have to brief the regular attending physician on events related to the patient's health within an appropriate time frame and in an appropriate manner.

(3)³⁰

Section 128

(1) To ensure that continuous care is available a healthcare worker obliged to provide in-area care shall, in keeping with employer rules and the provisions of separate statutes, beyond regular working hours

- a)³¹ be within reach, or in stand-by in a specific place, or
- b) provide on-duty services.

(2) With respect to Subsection (1)

- a) stand-by is defined as being prepared and ready to conduct work during out-of-the-ordinary working times, at a specific place accessible or designated by the healthcare provider,
- b) on-duty shall mean, if it is not necessary or possible to organize a regular work shift, availability to work at a work site during out-of-the-ordinary working time in return for an on-duty fee, as well as to conduct both on-duty tasks and tasks falling within the healthcare worker's job description.

Choice of Methods of Examination and Therapy

Section 129

(1) It shall be the right of the attending physician to choose freely among the scientifically accepted methods of examination and therapy [as set forth in Paragraph b) of Subsection (3) of Section 119], within the framework of valid statutes, that are to be applied, are known to and practiced by him or the persons participating in the care and that can be carried out under available objective and personnel conditions.

(2) The prerequisite for applying the method of examination and therapy chosen shall be that

- a) the patient has consented to it within the rules of this Act, and
- b) the risk of the intervention is lower than the risk of non-completion of the intervention, or that there be a well-founded reason for taking the risk.

(3) When performing /his tasks, the attending physician shall be authorized to

- a) request the participation of another physician or healthcare worker with other qualifications in the examination or treatment of the patient,
- b) recommend or convene a consultation.

³⁰ Repealed by Paragraph c), Subsection (2), Section 24, Act LXXI of 1999. Ineffective as of 1 August 1999.

³¹ Established by Paragraph e), Subsection (3), Section 24, Act LXXI of 1999. In force as of 1 August 1999.

Section 130

(1) The attending physician, in his area of responsibility, shall be authorized to issue instructions to healthcare workers participating in patient care. The instructions shall include a clear specification of the task to be completed, the place and time of completion, and, if necessary, the names and sphere of activity of additional healthcare workers to be requested to participate.

(2) The healthcare worker participating in the care shall

a) execute the instructions in accordance with the conditions set forth in them and in keeping with the code of practice of the profession,

b) immediately notify the attending physician, or if this is impossible, another physician participating in the care of the patient, if an unforeseeable event or event leading to a deterioration in patient condition occurs during implementation,

c) immediately make it known to the attending physician, or if this is impossible, to another physician participating in the care of the patient, if in his opinion, execution of the instructions would have an unfavorable influence on the condition of the patient, or if he has some other concern,

d) refuse to execute the instructions, simultaneously notifying the attending physician, if, according to knowledge he is expected to possess, compliance would threaten the life of the patient or lead to permanent impairment to patient's health that would otherwise not be a necessary outcome of treatment.

(3) The participating healthcare worker, if instructed to execute the instruction despite the provisions set forth in Paragraph c) of Subsection (2), shall be authorized to request that said instructions be communicated in writing.

(4) Within the framework of the instructions, the healthcare worker, in keeping with his own professional competency and experience, shall make his own decisions on the manner and order of executing the tasks he is to complete.

The Right to Deny Care

Section 131

(1) A physician directly involved in patient care may refuse to examine a patient seeking care

a) if prevented from doing so because of the immediate need to care for another patient or

b) because of a personal relationship with the patient

on condition that he refers the patient to another physician.

(2) A physician may refuse to examine and provide further treatment for a patient if his own health or some other obstacle renders him physically unfit to do so.

(3) A physician may refuse to provide care for a patient only following an examination, if in the course of the examination he determines that

a) the patient's health status does not require medical care,

b) the treatment requested by the referring physician or the patient is not justified professionally,

c) the healthcare provider does not have the personnel or objective conditions needed to provide the care and he refers the patient to a professionally responsible healthcare provider, or

d) the condition of the patient does not require immediate intervention and the physician completing the examination can order the patient to return at a later time, or the physician acts in accordance with Paragraph b).

(4) If, during the course of examining the patient, it is concluded that the treatment recommended by the referring physician or the patient is in conflict with the statutes or with professional rules, the physician may deny care.

(5) A physician also may refuse to treat a patient if

a) said treatment is in conflict with the physician's moral outlook, conscience, or religious convictions,

b) the patient seriously violates his obligation to cooperate [Subsection (2) of Section 26],

c) patient behaves in a manner that insults or threatens the physician, unless this behavior can be attributed to the disorder,

d) patient behavior puts the life or physical well-being of the physician at risk.

(6) In the cases set forth under Paragraphs a) and c) of Subsection (5), the physician only may refuse care if

a) said refusal will not damage patient health, and

b) he refers patient to another physician, or recommends that the patient see another physician in his own interests.

Section 132

(1) A healthcare worker who is not a qualified physician must deny care requested by a patient if

a) provision of said care conflicts with statutes or professional rules,

b) physically unfit to provide it because of his own state or health or other obstacle.

(2) A healthcare worker who is not a qualified physician may refuse care within his sphere of competence for causes set forth in Subsection (5) of Section 131, when simultaneously notifying the attending physician.

Section 133

When a healthcare worker is employed by a healthcare provider with obligation to provide in-area care, the condition for exercising the right of refusal set forth in Paragraph a) of Subsection (5) of Section 131 shall be the notification of the employer in writing of this circumstance prior to commencing employment or immediately following the occurrence of the circumstance during the course of employment.

Obligation to Provide Information

Section 134

(1) With the exception of cases set forth in Subsections (1) - (2) of Section 14, the attending physician shall brief the patient on his medical condition to the best of his knowledge, with the regularity justified by the condition, in keeping with the level of knowledge expected of the physician, and in accordance with the provisions set forth in Section 13.

(2) If the patient's disposing capacity is severely impaired or limited, the attending physician also shall inform the persons set forth in Subsection (2) of Section 14 or Section 16.

(3) Receipt of general informative leaflets prepared in bulk shall not substitute for a provision of oral information.

(4) In appropriate cases the information shall include the circumstances set forth in Subsections (1) and (5) of Section 209, Paragraph e) of Subsection (1) of Section 210, and Paragraph e) of Subsection (2) of Section 219.

Section 135

(1) The attending physician shall be circumspect in informing the patient, and shall do so gradually when necessary, considering the patient's condition and circumstances.

(2) When informing the patient, special attention shall be given to the generally known, significant side effects of treatment, to possible consequences, and to possible outcomes of interventions including the frequency with which they occur. The physician shall ascertain that the patient has understood the information, and when necessary the physician shall see to it that the patient so informed shall have psychological care.

Obligation to Document

Section 136

(1) The healthcare documentation shall contain data related to patient's examination and treatment. Clinical charting shall be conducted in a manner that reflects the true course of the healthcare process.

(2) Healthcare documentation shall include

- a) patient identification data,
 - b) if a patient is in possession of full disposing capacities, a person to be notified in case of emergency, or in the case of a minor or a person with a guardian, the name, address, and manner of accessing said patient's legal guardian,
 - c) patient's history, and the etiology of the disease,
 - d) the results of the initial examination,
 - e) the results of examinations/test serving as a basis for diagnosis and therapy, and the dates on which said examinations/tests took place,
 - f) the name of the disease justifying care, the underlying diseases, comorbidities, and complications,
 - g) the names of other illnesses not directly requiring care, and of the risk factors,
 - h) the time and results of interventions,
 - i) pharmaceutical and other therapies, and the results,
 - j) patient data on over-sensitivity (allergies) to medications,
 - k) the name of the healthcare worker recording the information on the chart, and the date on which it was charted,
 - l) a statement of the information provided to the patient and/or to other persons authorized to receive said information,
 - m) the fact of patient consent [Subsection (3) of Section 15] or denial of consent (Sections 20-23), and the date(s) on which it (they) occurred,
 - n) all other data and facts that can influence treatment outcome.
- (3) The following shall be maintained as a part of healthcare documentation:

- a) findings from all laboratory tests,
- b) documents written during the course of treatment and during consultations,
- c) nursing care documents,
- d) copies of images taken during imaging diagnostic procedures, and
- e) findings of tests on tissue samples taken from the patient's body.

Section 137

At the conclusion of a therapeutic procedure consisting of several parts or following care in an inpatient facility, a written summary report (discharge summary) shall be prepared and, excepting the case as set forth in Subsection (1) of Section 14, this report shall be given to the patient.

Obligation to Maintain Confidentiality

Section 138

- (1) All healthcare workers and all persons employed by a healthcare provider shall be obliged to maintain unlimited duration confidentiality regarding the health of a patient, as well as regarding all data learned while providing healthcare services, irrespectively of whether said data was provided directly by the patient, or learned through an examination/test or through treatment, or learned indirectly through medical documentation or in any other manner.
- (2) The requirement for confidentiality shall not cover cases in which the patient has given a release, or for which statutes specify an obligation to provide said data.

Protection of Healthcare Workers

Section 139

A healthcare worker and all other workers employed by a healthcare provider qualify as persons performing a public service when performing any of the following:

- a) issuing medicolegal expert report,
- b) judging fitness or unfitness to work or the degree to which working ability has been impaired,
- c) judging fitness to perform a job or work in a given occupation,
- d) conducting examinations as part of a procedure to grant a permit linked to physical fitness,
- e) conducting examinations to determine eligibility for other healthcare, health insurance or welfare services,
- f) performing mandatory public health measures,
- g) performing an examination or intervention at the request or on the orders of the authority,
- h) providing on-duty or emergency services.

The Right and Obligation to Develop Professionally

Section 140

A healthcare worker and other person employed by a healthcare provider has both the right and the obligation to continuously develop and advance his professional knowledge, in keeping with the current state of science and its advances.

Chapter VII

RESPONSIBILITY OF THE STATE FOR POPULATION HEALTH, THE ORGANIZATION AND ADMINISTRATION OF HEALTHCARE

Title 1

The Responsibility of the State for Population Health

Section 141

(1) Within the framework as specified in this Act, the state is responsible for the state of population health, and particularly for evolving the system of conditions needed for this , to make it possible for communities and individuals to maintain, protect and improve their health, and when necessary, to restore it to the extent possible.

(2) The content of state responsibility:

a) creating and maintaining the general conditions (organizational, institutional, educational, research) for a healthcare delivery system that is satisfactory in quantity, quality, distribution, composition, and effectiveness to allow individuals to exercise their right to healthcare,

b) ensuring the operation of a statutory health insurance system so that the individual may exercise his right to healthcare.

c) fully protecting and guaranteeing the right to human dignity and self-determination when operating the healthcare institutions,

d) defining and implementing the system of health policy objectives, tasks and implements.

(3) Within the sphere of state responsibility, the central government is particularly mandated

a) to provide the basic conditions for health promotion and health improvement,

b) to define the healthcare delivery system, as well as the obligation and responsibility to provide healthcare,

c) to evolve and develop the financing, development, and information systems that serve the goals of health policy,

d) to define the system of professional requirements on healthcare services, including the system of quality assurance and control of healthcare services,

e) to regulate and ensure the conditions for the systems of basic, postbasic and continuing education in health,

- f) to support, organize, and coordinate health research,
- g) to integrate information needed to adopt a healthy lifestyle into the education system,
- h) to protect the public interest over individual interest in cases defined in this Act,
- i) to coordinate individual and societal interests when applying rare, highly costly, and new methods and procedures,
- j) to provide ambulance and emergency services and disaster health services, to manage the national blood supply,
- k) to provide the conditions for public health and health administration activity.

Section 142³²

- (1) The state shall provide funding for healthcare services, satisfactory in level and quality, through the central budget and the Health Insurance Fund budget.
- (2) Unless declared an exception by law, the central budget shall cover the related costs of the following types of service and tasks:
 - a) ambulance and emergency services,
 - b) disaster health services,
 - c) services related to organizing the blood supply and making blood available,
 - d) the use of rare or exceptionally costly therapeutic procedures, or therapeutic procedures that are a part of biomedical research,
 - e) the public health tasks set forth under Sections 35-36,
 - f) mandatory public health and epidemiological tasks,
 - g) within the framework of public health activities aimed at primary prevention, tasks involving health promotion and improvement, the organization of health education, and family planning counseling,
 - h) prenatal care and care for mothers post partum,
 - i) state support for professional education and mandatory continuing education in health,
 - j) payment of damages that are incumbent on the State based on this Act,
 - k) cost reimbursement incumbent on the State based on the Act [Section 70 and Subsection (2) of Section 204], and
 - l) tasks set forth under separate statute or by government decree authorized by statute.
- (3)³³ All Hungarian citizens permanently or temporarily resident in Hungary and all non-citizens qualifying as equivalent in terms of insurance coverage, furthermore non-citizens entitled to services on the basis of international contracts shall be entitled to the services set forth in Paragraph d) of Subsection (2) at the expense of the central budget.

Title 2

Organization and Administration of the Health Service

³² In effect as of 1 January 1998

³³ Inserted by Section 11, Act LXXI of 1999. In force as of 1 August 1999.

Section 143

Responsibility for health service organization and administration tasks, and for exercising related rights and meeting obligations, as set forth in this Act, shall rest with Parliament, the Government, the Minister of Health, NPHMOS, and the local governments, as well as the health insurance bodies, and the bodies maintaining the healthcare institutions.

Section 144

(1) The state shall use its available means to support and promote the activities, pursuant to the content of this Act, of the professional chambers and other public bodies operating in the health field, as well as those of the professional bodies that represent interests, of professional associations and of other social organizations.

(2) The state shall cooperate with the bodies set forth in Subsection (1) to promote implementation of the objectives and fundamental principles set forth in this Act to improve population health and quality of life, and to successfully combat health damaging environmental, social, and other impacts.

Parliament

Section 145

In connection with health services, the Parliament of the Republic of Hungary shall

- a) consider and enforce, in the course of its activity, national interests to promote public health and related health policy objectives,
- b) adopt the National Health Improvement Program, and shall evaluate implementation of the measures set forth in said program as well as the overall state of public health.

National Health Improvement Program

Section 146

(1) The National Health Improvement Program (hereinafter: NHIP) shall serve as the foundation for healthcare planning. The factors set forth in the NHIP shall be supported in making and executing all decisions of economic planning, regional and settlement development, and all areas involving state planning.

(2) The NHIP shall include

- a) a presentation of the state of the nation's health, particularly focused on the highly critical areas,
- b) a definition of health improvement and health promotion targets,
- c) the tasks required to meet the targets and the order of implementation,
- d) the means required to meet the targets, with particular respect to financial resources.

3) The NHIP shall be revisited at least every four years.

Government Tasks

Section 147

- (1) Within its sphere of obligations related to health service organization and administration, the Government shall
- a) be responsible, through the Minister of Health, for preparing the NHIP and submitting it to Parliament,
 - b) set the principles, objectives and major trends of health promoting public policies, and within them, of health policy,
 - c) control and coordinate implementation of healthcare-related government administration tasks,
 - d) be responsible for fulfillment of obligations set forth in international treaties related to healthcare, and for the exercise of rights therefrom,
 - e) be responsible for fulfillment of damage and restitution obligations for which the state is liable under this Act,
 - f) arrange, in cases of disaster [Subsection (2) of Section 225], for providing the conditions to fend off the danger, and to provide general leadership for defensive activities.
- (2) The Government shall provide legislative supervision for the activities of the health insurance bodies, pursuant to provisions of a separate statute.

National Healthcare Council

Section 148

- (1) The National Healthcare Council (hereinafter: Council) shall assist the Government in meeting its health organizational and administration tasks.
- (2) The Council shall
- a)³⁴ take initiatives, make recommendations, offer opinions, and serve as advisor to the Government in shaping its health policies,
 - b)³⁴ analyze and evaluate the processes through which government health policy decisions are implemented.
- (3) The Council shall participate
- a) in shaping and executing the NHIP,
 - b) in shaping government level health promoting public policies and preparing decisions,
 - c) in elaborating and enforcing health policy targets and tools,
 - d) in defining public health tasks and the order of implementation.

Section 149

- (1) The members of the Council shall be:
- a) one delegate from each of the national professional chambers operating in the field of healthcare,
 - b) three persons delegated by national organizations that represent the interests of healthcare workers,
 - c) ten persons delegated by national patient advocacy organizations,
 - d) three persons delegated by the national alliances of local governments,
 - e) three persons delegated by the national alliances of healthcare providers,

³⁴ Amended by Paragraph d), Subsection (2), Section 24, Act LXXI of 1999.

- f) three persons delegated by the healthcare educational institutions,
 - g) one person from each of the ministries that maintain healthcare institutions,
 - h) one person designated by the National Inspectorate of Labor Safety and Labor Affairs,
 - i) one person designated by the Hungarian Academy of Sciences, and
 - j) two persons delegated by scientific societies operating in healthcare.
- (2) In addition, by virtue of this Act, the following also shall be members of the Council:
- a) the Minister of Health,
 - b) the Chief Medical Officer, and
 - c)³⁵ the person cited in Subsection (2) of Section 1 of Act 39 of 1998 on Government Supervision of the Social Insurance Funds and the Social Insurance Bodies.
- (3) The Council shall choose a Chair from among its members. By virtue of this Act, the Minister of Health, as representative of the Government, shall serve as co-chair.
- (4) The funding for the operation of the Council shall be provided from the chapter of the central budget devoted to the Ministry of Health.
- (5) The Government shall determine the detailed rules that set forth the Council's tasks, organization, and operations.

Responsibilities of the Minister of Health

Section 150

- (1) The Minister of Health shall supervise the health sector in keeping with the provisions of this Act and Government health policy decisions. In particular, the Minister shall
- a) perform the sectoral tasks set forth by the NHIP,
 - b) perform the professional tasks related to basic, postbasic, specialization and continuing education in health,
 - c) define the system of professional requirements for healthcare services,
 - d) support and coordinate scientific research affecting the scope of duty of the health sector,
 - e) manage the registration and information system required for the sectoral management and uniform operation of healthcare activity,
 - f) guide the NPHMOS through the Chief Medical Officer,
 - g) guide the national institutes of health,
 - h) define and coordinate activity related to the production, marketing and prescription of pharmaceuticals, and medical appliances.
- (2) The sectoral authority of the Minister shall extend to all healthcare activities and all healthcare providers, regardless of their legal status.
- (3) The activity of the Minister of Health shall be assisted by the Medical Research Council (hereinafter: MRC), by professional colleges, and by the national institutes set forth under Paragraph g) of Subsection (1).

³⁵ Established by Section 36, Act XCI of 1998. In force as of 1 January 1999

Responsibilities of the National Public Health and Medical Officer's Service

Section 151

- (1) The central and regional bodies of the NPHMOS shall implement Government tasks and exercise Government authority as set forth in this Act and other statutes in the frames of public health and health administration and coordination.
- (2) The major rules governing the organization and operation of the NPHMOS are set forth under separate statute.

Responsibilities of Local Governments

Section 152

- (1) Within primary health care, the local governments of settlements shall arrange for the provision of
 - a) family practitioner and family pediatric practitioner care,
 - b) primary dental care,
 - c) on-duty services related to primary healthcare,
 - d) health visiting,
 - e) school health services.
- (2) The representative bodies of the local governments of settlements shall define and draw up the primary healthcare districts, and when services are provided to more than one settlement as parts of a district, it shall define the seat of the district.
- (3) The local governments shall be responsible for the operation of the specialized outpatient clinics and the healthcare institutions providing specialized inpatient services that they own or use.

Section 153

- (1) Among the various environmental and settlement health responsibilities, the local government shall arrange for
 - a) meeting public sanitation and settlement sanitation tasks,
 - b)³⁶ extermination of insects and rodents as defined by separate statute, and set forth in Subsection (1) of Section 73.
 - c) the continuous monitoring of the environmental health situation of the settlement, and in case of a deterioration, shall take measures within its own sphere of authority, insofar as it is able to do so, or shall call upon the responsible authority with jurisdiction to act, initiating the appropriate measures.
- (2) The representative bodies of the local governments of settlements shall make decisions on the extraction and management of therapeutic mud and the products of therapeutic springs, and on the bottling, packaging, and distribution of recognized therapeutic water, therapeutic mud and products of therapeutic springs, or shall grant permits for conducting said activities.

³⁶ Established by Section 12, Act LXXI of 1999. In force as of 1 August 1999.

Responsibilities of the Health Insurance Bodies

Section 154

The health insurance bodies shall be obliged to ensure, with regard to health services delivered by healthcare institutions,

- a) securing necessary capacities in due time, and
- b) financing of services that have been delivered and reviewed, as set forth under separate statute.

Maintenance of Healthcare Institutions

Section 155

- (1) The bodies which maintain healthcare institutions shall, in particular, be authorized to
 - a) exercise the right to found, establish, reorganize and close down said institutions,
 - b) exercise rights related to the budgets of said institutions,
 - c) exercise the rights of employer with respect to the managers (deputy managers) of said institutions,
 - d) approve documents regulating the operation of said institutions (e.g. rules of organization and operation, house rules),
 - e) monitor and supervise operation of the institution.
- (2) As part of the obligation to provide in-area care and in keeping with the provisions of separate statute, the bodies which maintain healthcare institutions shall ensure that the healthcare institution they maintain
 - a) have the professional conditions necessary to provide healthcare services and
 - b) are kept operable and are further developed.

Section 156

- (1) Specialized inpatient healthcare institutions with an obligation to provide in-area care shall have hospital supervisory boards and hospital ethics committees operating within them.
- (2)³⁷ Specialized inpatient healthcare institutions not coming under the provisions of Subsection (1) may establish hospital supervisory boards and hospital ethics committees, by applying the rules set forth under separate statute as appropriate.
- (3)³⁷ The roles of the hospital supervisory board in specialized inpatient healthcare institutions shall be to
 - a) voice opinions and make recommendations on issues related to operation, maintenance and development of the institution,
 - b) ensure that contact is maintained between the management of the institution and the public,
 - c) represent the interests of the population served in the operation of the institution, and
 - d) monitor the operation of the institution
 with respect to healthcare services delivered by the institution.

³⁷ Established by Section 13, Act LXXI of 1999. In force as of 1 July 1999.

(4)³⁸ The hospital supervisory boards shall be composed of nine, twelve, or fifteen members. More than half of the members shall be elected from among delegates of social organizations operating in healthcare within the catchment area of the healthcare institution, and the other members shall be elected from among delegates of the institution. The board chair shall be elected from among the delegates of the social organizations.

(5)³⁹ For healthcare institutions owned by local governments, Subsection (4) shall be applied with the difference that a maximum of one-third of the members shall be elected from among delegates of the local governments of the catchment area of the healthcare institution, while one-half of the additional members shall be elected from among the delegates of the social organizations as set forth in Subsection (4), and the other members shall be elected from among delegates of the institution.

(6)⁴⁰ The roles of the hospital ethics committee shall be to

- a) take positions on ethical issues that arise within the institution,
- b) participate in enforcing patient rights,
- c) grant approval in the exceptional cases involving organ and tissue transplants as set forth in this Act,
- d) see to tasks relegated to the committee by the institution's rules of organization and operation (house rules).

(7)⁴⁰ The hospital ethics committee shall have a minimum of five and a maximum of eleven members. Its members shall be invited by the management of the healthcare institution, with the constraint that the composition of the committee shall offer a manifold (medical, psychological, legal, religious, etc.) approach to issues.

Chapter VIII

BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Section 157

The objective of biomedical research involving human subjects (hereinafter: research) is to improve detection of the causes and origins of diseases and to facilitate treatment, prevention, and rehabilitation, and shall include interventions and modes of observation that deviate from the ones applied in usual healthcare services, or ones that apply factors (active ingredients, materials, implements, procedures, methods, circumstances, conditions) that have not yet become fully known or completely investigated.

Section 158

(1) Research may be conducted within the framework set forth in this Act, with the differences as set forth under separate statute with regard to clinical research on pharmaceuticals.

(2) The professional conditions and detailed rules for research shall be set forth by the Minister of Health, who shall consider the opinion of the MRC.

³⁸ Established by Section 13, Act LXXI of 1999. In force as of 1 July 1999

³⁹ Inserted by Section 13, Act LXXI of 1999. In force as of 1 July 1999

⁴⁰ Numbering amended by Section 13, Act LXXI of 1999.

Section 159

(1) Research on persons with full disposing capacities shall be conducted exclusively for proposes of perfecting diagnostic, therapeutic, preventive, and rehabilitation procedures, of elaborating new procedures, and of gaining a better understanding of the etiology and pathogenesis of disease, and shall be conducted by a healthcare services provider with the appropriate professional conditions to meet the requirements of the nature and risks of the research, but only if all of the following conditions are met:

- a) the research plan has been approved for implementation;
- b) preliminary investigations have certified the effectiveness and safety of the research;
- c) there is no other procedure similar in effectiveness to research involving human subjects;
- d) the risks of conducting the research on a person are proportionate to the expected benefit of the research, or to the significance of the research goal;
- e) the research subject, after being fully informed in accordance with Subsection (3), has provided written consent to the research.

(2) Research shall not be conducted if it presents a disproportionately high risk to the life, or physical or emotional well-being of the research subject.

(3) Prior to obtaining the consent of the research subject, he shall be informed orally and in written form of

- a) the voluntary nature of participation in research, as well as of the fact that his consent may be withdrawn at any time without specifying cause or suffering any prejudicial consequences;
- b) the experimental nature of the planned examination or intervention, of its objectives, and of its duration;
- c) the nature, duration, and possible risks and consequences of the examinations or other interventions performed as part of the research, as well as of all the discomfort involved;
- d) expected benefits of the research to the subject or to others;
- e) possible other examinations or interventions that are available instead of participating in the research;
- f) the nature and treatment of any damage to health sustained in conjunction with the research, and of damages or compensation available;
- g) the names of the person(s) responsible for the research.

(4) Research involving a person with impaired or limited disposing capacity may be conducted only if all of the following conditions are met:

- a) the conditions set forth under Paragraphs a) - d) of Subsection (1) are met;
- b) the results of the research can have an immediate beneficial effect on the health of the research subject;
- c) the research cannot be conducted effectively on a person who possesses full decision-making capacities;
- d) the person set forth in Subsections (1) - (2) of Section 16 has consented to the research, in keeping with the provisions of Subsection (5) of Section 16.

(5) Under exceptional circumstances, the condition set forth under Paragraph b) of Subsection (4) may be waived if all of the following conditions are met:

- a) the objective of the research is to enhance scientific knowledge related to the condition or disease of the research subject in a manner that is useful to said research subject or to other

persons who are similar in age and suffering the same disease, or who demonstrate similar characteristics and are in a similar state of health;

b) the risk of the research on the subject does not significantly exceed minimum, and the strain is mild;

c) the Minister of Health has granted permission for the research after hearing the opinion of the MRC.

(6) The research plan shall be approved for implementation by the executive of the healthcare institution, or in the case of another health service provider, by the executive of the regionally responsible Budapest or county inpatient institution, after receipt of the opinion of an independent professional and ethics committee made up of specialists in medicine, law, theology, ethics, and psychology, as defined in the Minister of Health Decree, in keeping with said opinion. If the committee rejects the proposal, the executive of the healthcare institution may submit a request to the MRC to revisit the opinion.

Section 160

In the case of an emergency, if the consent of the research subject or the person set forth in Subsections (1) - (2) of Section 16 cannot be obtained, exclusively an emergency experimental treatment expected to directly benefit the health of the research subject may be applied, if the research treatment can be applied within the framework of a research plan that has been granted previous approval.

Section 161

(1) An expectant or breast-feeding woman only may be used as a research subject if the research is expected to be of direct benefit to her or her child, or to the health of women and children in a similar phase of life, and if there is no procedure that would make it possible to conduct research with a similar outcome on women who are not expectant or breast-feeding.

(2) No research shall be conducted on persons or groups of persons who are not in a position to freely consent to said research, because of considerations that put said persons in a state of financial or moral dependence on factors connected to the research or researchers, or if they are dependent on them for services.

(3) Research shall not be conducted on any person restricted in liberty or performing mandatory military service, even if they should consent to same. A person restricted in liberty but in possession of full disposing capacities may only, under this Act, be used as a subject for research if said research is of immediate and significant benefit to the person's own health or to the health of an immediate family member or to that of a person in a similar situation, and if similar research results cannot be expected if conducting said research with persons who are not restricted in liberty as set forth in this Act.

(4) The Minister of Health, who shall consider the opinion of the MRC, shall grant permission to conduct research set forth under Subsections (1) - (3) .

Section 162

Research or interventions aimed at or resulting in modifications in the human genome shall be conducted only for preventive, diagnostic or therapeutic purposes and, with the exception of the provisions set forth under Subsections (1)-(2) of Section 182, shall be conducted only when the objective is not to alter the genetic complement of progeny or to bring about a new individual.

Section 163

In the course of research, the interests of the individual shall always have priority over the interests of science and society; therefore, the risk to the research subject shall be restricted to the lowest level possible.

Section 164

(1) In the event a research subject participating in research conducted in accordance with professional rules and the approved research plan suffers injuries or dies during the research, the state shall provide compensation to the subject or to his dependants.

(2)⁴¹ Prior to beginning the research, the institution conducting the research shall have contracted for liability insurance specific to the research, in an amount corresponding to the risks involved.

Chapter IX

SPECIAL PROCEDURES TARGETED AT HUMAN REPRODUCTION, RESEARCH CONDUCTED USING EMBRYOS AND REPRODUCTIVE CELLS, STERILIZATION PROCEDURES

Section 165

For the purposes of this chapter

- a) *embryo*: all live human embryos from the conclusion of fertilization until the 12th week of gestation,
- b) *fetus*: all intra-uterine humans from the 12th week of gestation.

General Conditions of Special Procedures Targeted at Human Reproduction

Section 166

(1) Special methods that may be applied to human reproduction (hereinafter: reproduction procedures) are

- a) in vitro fertilization and embryo implantation,
- b) artificial in vivo fertilization using the sperm of the spouse or common-law spouse, or donor sperm,
- c) in vitro fertilization using donor sperm and embryo implantation,
- d) implantation of donated embryos
- e)⁴²
- f) other methods to promote fertilization of female reproductive cells, to enhance the ability of said cells to become fertilized, and to promote the adhesion and development of fertilized reproductive cells.

(2) Only human reproductive cells or human embryos shall be used in fertilization and in embryo implants in the course of reproduction procedures.

⁴¹ Amended by Paragraph f), Subsection (3), Section 24, Act LXXI of 1999.

⁴² Repealed by Subsection (1), Section 32, Act CXIX of 1999.

- (3) Reproductive cells from deceased parties, including from persons who are brain-dead, or from dead fetuses, shall not be used in reproduction procedures.
- (4) The provisions of Sections 170-174, and/or Sections 175-179 shall take precedence in the donation of reproductive cells and/or embryos.
- (5)⁴³ Only the methods set forth in Subsection (1) shall be applied as reproduction procedures.

Section 167

- (1) Reproduction procedures may be performed on married couples or on two persons of opposing genders living together as common-law spouses if, for reasons of health existing among either party (infertility), it is highly probable that a healthy child cannot be produced through natural means. Among common-law spouses, the procedures only may be conducted if neither of the partners is married to another person.
- (2) If the female reproductive cell already has been fertilized, the reproduction procedure may be continued by a woman who has become single by termination of the marriage (common-law) relationship. If, however, the fertilization was in vitro and the embryo has not yet been implanted, prior to the beginning of the reproduction procedure the married (common-law) couple may expressly preclude continuation of the procedure for the event of the death of the spouse (common-law spouse) by submitting a joint request focused on this eventuality as per Subsection (1) of Section 168.
- (3) The reproduction procedures set forth in Subsections (1) - (2) only shall be performed when other methods of treating infertility have proven unsuccessful and when there is a medically founded chance that a healthy child will be conceived and born as a result of the procedure.
- (4) Reproduction procedures may be conducted on recommendation of a competent specialist physician, and by a health service provider authorized to conduct said procedures in its operation license.

Section 168

- (1)⁴⁴ A reproduction procedure, or in the case of a single woman, continuation of said procedure, shall occur at the joint written request of the married or common-law couple or of the single woman, in absence of a declaration of preclusion as set forth in Subsection (2) of Section 167, and within the framework of the law on disposition over an embryo that has been deposited. The request shall be formulated as a private legal document of full evidentiary validity. Common-law spouses shall submit a statement of their common-law relationship in the form of an official document.
- (2) Prior to beginning the procedure, the physician conducting the procedure or a member of the medical team shall meet with the applicants, who shall appear together and in person, and provide oral and written information on the reproduction procedures that can be conducted in their given case. The information shall include, in particular:
 - a) the medical indications for the procedure;
 - b) the nature of the procedure that can be performed, possible further and additional medical interventions that may become necessary during execution;
 - c) the effects of drug treatment necessary prior to performing the intervention;

⁴³ Inserted by Section 16, Act CXIX of 1999. In force as of 1 January 2000.

⁴⁴ Established by Section 14, Act LXXI of 1999. Amended by Subsection (1), Section 32, Act CXIX of 1999.

- d) the effects and possible risks to the unborn child and/or the subjects of the intervention;
- e) the expected results of the procedure;
- f) the expected costs of submitting to the procedure;
- g) the statutes regulating execution of the procedure.

(3) When informing the patient as set forth under Subsection (2), general rules on providing information to patients as set forth in this Act shall have precedence, however, the spouse or common-law spouse not participating directly in the intervention also shall be entitled to the legal status of patient. If several of the reproduction procedures set forth in Subsection (1) of Section 166 may be applied, the information shall cover all procedures that can be conducted and shall also include a concrete medical recommendation for one of the procedures.

(4) The reproduction procedure only shall be begun on receipt of a joint written statement of consent written after they have been informed, or - in the case of a single woman - shall only be continued after a written statement of consent from the applicant has been received.

(5) Only a person in full possession of his disposing capacity shall be entitled to make the legal declarations set forth in Subsections (1) and (4).

Section 169

(1) A Minister of Health Decree shall set forth the professional conditions for the operation of healthcare providers authorized to conduct reproduction procedures, the set of health indications serving as the basis for the various interventions, and the detailed professional rules for performing the healthcare interventions.

(2) Operation license to perform reproduction procedures shall be awarded only to health service providers which can simultaneously meet the professional requirements set forth under separate statute for the frozen storage of reproductive cells and embryos.

Donating and Depositing Reproductive Cells

Section 170

(1) Reproductive cells may be donated for use in reproduction procedures or for medical research, and shall be used only for the purpose specified by the donor.

(2) When conducting a reproductive procedure, the reproductive cells used shall all come from the same donor.

(3) Remuneration for donating reproductive cells shall not be requested or provided. Donation-related necessary and certified costs of a donor, including loss of income, shall be reimbursed, within the sphere and under the conditions set forth by Minister of Health Decree.

Section 171

(1) Reproductive cells may be donated by any person in full possession of his disposing capacity, when cells are donated for a reproductive procedure, by persons under the age of 35 years, who meets the conditions set forth under separate statute.

(2) Reproductive cells for reproduction procedures or for reproductive cell research can be donated directly to healthcare providers and/or research facilities authorized to conduct reproduction procedures or reproductive cell research. Natural persons, legal entities, or unincorporated organizations that are not authorized to conduct reproduction procedures or

research shall not accept human reproductive cells or materials containing said cells as donations, and cannot claim ownership to same.

(3) The donation set forth under Subsection (2) shall occur by providing a written declaration of donation to the health service provider or research facility authorized to accept reproductive cells and by appearing in person at the institution for harvesting the substance containing the reproductive cells. When donating the cells for a reproduction procedure, the donor's declaration shall contain the name of the donor (family and given name, maiden name), mother's maiden name, address, date of birth, gender, physical description, and all illnesses of which the donor is aware.

(4) The health service provider to which a donation has been offered, prior to harvesting the reproductive cells being donated for reproductive procedures, shall see to it that the donor, who has appeared in person, undergoes a preliminary medical examination, and shall orally inform the donor of the purpose and conditions of the donation. When appearing in person, the donor shall credibly certify the correctness of the personal data submitted.

(5) A donor declaration and preliminary medical examination as set forth in Subsections (3) and (4) are necessary only prior to the first harvesting of reproductive cells, if the donations of reproductive cells are made repeatedly, on an ongoing basis. The ongoing nature of the donations does not exempt the donor from providing information on any known illnesses.

(6) The health service provider or research facility authorized to accept donations of reproductive cells may reject the donation without specifying cause. Donations offered for reproductive procedures shall be rejected if

- a) the donor has a disease which precludes donation;
- b) the donor refuses to provide the personal and special data set forth in Subsection (3) and if the data cannot be learned in another credible manner;
- c) the donation is made in a manner other than by harvesting of substance containing reproductive cells during a personal appearance before the health service provider that is competent by the place of donation.

(7) All persons and bodies shall be obliged to take measures resulting in the immediate destruction of reproductive cells or substances containing reproductive cells coming into their possession through donations made in an unauthorized manner or coming into their possession through donations made in an authorized manner but rejected on the basis of Subsection (6).

Section 172

(1) All personal and special data learned by the health service provider or the research facility through the provisions of Subsection (3) of Section 171 or the personal appearance and examination of the donor, shall be managed in accordance with the provisions of Act 63 of 1992 on the Protection of Personal Data and the Publicity of Data of Public Interest, and of Act 47 of 1997 on the Handling and Protection of Health Data and Related Personal Data, with due consideration for Subsections (2) - (4).

(2) The health service provider shall handle only the personal and special data listed under Subsection (3) of Section 171 in relation to donations of reproductive cells. In the course of data management, with respect to personal data, information on name and address shall not be transferred but all other data, treated so that it cannot be used to identify a person, may be transferred to the bodies or persons defined in Subsection (3). A reproductive service provider learning of data that is outside the scope of lawful data management shall take immediate measures to destroy said data.

(3) In the course of data management as set forth under Subsection (2), personal and special data may be provided to other healthcare providers authorized to conduct reproduction procedures, or to persons authorized to make use of reproduction procedures, with the restrictions set forth in Subsection (2).

(4) Of the data learned in connection with the donation of reproductive cells, research facilities may manage only data specific to the state of health, and the illnesses of the donor. The right to manage data includes maintaining records of the data that are authorized to manage in a manner that prevents personal identification, and transferring or disclosing said data only as it relates to the objectives and/or results of medical research.

Section 173

(1) A health service provider only may provide reproductive cells donated for reproductive procedures in order to conduct said procedure and only to the extent made necessary by the procedure, under the restrictions set forth in Subsection (2), either for procedures that it shall conduct or for procedures conducted by another healthcare provider authorized to conduct reproductive procedures.

(2) When providing reproductive cells, it shall be ensured that the number of progeny from one and the same reproductive cell donor shall not exceed four, even when reproductive procedures are performed on different persons. Reproductive cells used in a single reproductive procedure shall all come from the same donor.

(3) Prior to issuing donated reproductive cells, when the reproductive procedure is being performed by another health service provider, using the data made available by the institution conducting the intervention, the health service provider storing the reproductive cells shall ascertain that the reproductive cells can be used for the given reproduction procedure, and determine the absence of any possible biological incompatibility. The persons applying for the reproductive procedure shall provide data suitable for identification to the facility conducting the investigation, if this is necessary to complete the investigation.

(4) The health service provider handling the storage of the reproductive cells shall provide no information on the circumstances under which the reproductive cells were transferred or on the data of persons involved in their use, and shall not transfer any such data, or disclose any of it.

(5) A research facility only may transfer reproductive cells for purposes of medical research, and only to a healthcare provider or research facility authorized to receive reproductive cells.

Section 174

(1) The health service provider shall store donated and accepted reproductive cells by freezing them. Storage of reproductive cells can be precluded or limited in duration by the provisions of separate statute. On expiration of the limited duration, the stored reproductive cells shall be destroyed.

(2) On medical grounds and on recommendation of a specialist physician or when otherwise requested for cause, facilities may accept deposits of reproductive cells from persons in possession of full disposing capacities for frozen storage to be used by the depositor at a later date (reproductive cell deposits). Only reproductive cells coming from the depositor and personally harvested from depositor shall be accepted for storage.

(3) Reproductive cells that have been deposited may be provided to health service providers conducting reproduction procedures on the written request of the depositor. On the written

request of the depositor, the reproductive cells shall be destroyed before expiration of the storage time limit.

(4) In the course of storing reproductive cells, cells from different donors, cells from one and the same donor harvested at different times, cells donated for different purposes, and various samples of cells provided for deposit, shall not be mixed.

(5) Continuous records shall be kept on reproductive cells stored, and on the issuance, use or destruction of said cells. To maintain these records, the reproductive cells shall be stored in a manner enabling identification of the donor, or when stored for purposes of research, in a manner that does not enable identification of the donor, and each storage unit shall be affixed with an identification code.

Embryo Donations and Deposits

Section 175

(1) The married (common-law) couple shall jointly exercise the right of disposal over an embryo brought about in vitro for reproductive purposes until the death of one of the partners, irrespectively of any subsequent change in the spousal (common-law spousal) relationship, but either of the parties shall have the right to renounce the right of disposal in an official document or a private document with full evidentiary authority. When there is a difference of opinion, the rules of embryo deposit shall be appropriately applied.

(2) The married (common-law) couple participating in a reproduction procedure involving their own reproductive cells shall be jointly entitled to the right of disposal of an in vitro embryo brought about through reproductive cell donation, also in keeping with the provisions of Subsection (1).

(3) The right of disposal over an embryo set forth in Subsections (1)-(2) shall include the right to deposit it for possible later use (embryo deposit), or to donate it to other persons for use in a reproduction procedure, or to offer it to research. In the absence of proper provisions, or knowledge of said provisions, it shall be assumed that the intention was to deposit a healthy embryo.

(4) Embryos coming from identical persons shall be used in reproduction procedures on a maximum of two other persons.

Section 176

(1) An embryo can be offered through a written declaration by the persons authorized to decide upon its disposal, which shall include the objective of the offer and, when offered as an embryo donation, the ages and physical characteristics of the persons contributing to the embryo, and any illnesses known to the persons making the declaration.

(2) When offering and/or rejecting an embryo, the provisions of Subsection (2) of Section 171 shall be applied, as appropriate.

(3) The health service provider or research facility offered the embryo may reject the embryo offered if it is probable that it will not be able to use it for the purpose specified within the time frame under which it can be used, however, it shall be mandated to safeguard it and store it until use under Subsection (4). An offer of an embryo donation shall be rejected if it is not probable that a healthy child can develop from said embryo.

(4) Any body or person gaining possession of an embryo without the authority to do so, or with the authority to do so, but when the offer of the embryo has been rejected in accordance

with Subsection (3), shall be obliged to transfer the embryo to an authorized health service provider or research facility. A damaged embryo may only be transferred to a research facility. The possessor of the embryo must safeguard an embryo not transferred to another authorized facility, or to destroy a damaged embryo, pursuant to the provisions of Subsection (5).

(5) All healthcare providers and research facilities shall accept transfer of a viable embryo from a person or body clearly unauthorized to possess said embryo, and treat disposal of the embryo in keeping with the intent or assumed intent of the parties authorized to decide upon its disposal in keeping with Subsection (3) of Section 175.

Section 177

(1) Personal and special data learned by the healthcare provider or the research facility that is related to donations of embryos or donations for purposes of research shall be treated in accordance with data management for the donation of reproductive cells contained in this Act, with the constraint that in embryo donation procedures, only the data set forth under Subsection (1) of Section 176 shall be managed.

(2) In procedures involving embryo donations, management of data related to embryos and to the donation of reproductive cells learned in an authorized manner by healthcare providers and which is connected to personal and special data that can be managed in at least one of the procedures shall not be considered unauthorized management.

Section 178

(1) Release of embryos that have been donated or offered for research, storage of embryos by health service providers, and deposits of embryos shall be governed by the provisions of Subsections (1), and (4) -(5) of Section 173 and by Subsections (1) - (3), and (5) of Section 174 with the difference set forth in Subsections (2) - (3).

(2) An embryo shall be deposited upon measures taken by the person(s) authorized to decide upon its disposal, or on the basis of the assumed intention of that person (those persons) as set forth by this Act. Stipulation of the medical ground or other cause for depositing the embryo shall not be necessary.

(3) An embryo that has been deposited shall be released only on the basis of a written declaration expressing the agreement of both parties with the right to decide on disposal, except in the case of the death of one party, or a renunciation of said rights.

(4) An embryo shall be released to a single woman with the right to decide upon disposal following the death of her spouse (common-law spouse) for purposes of implanting, in the absence of a declaration precluding this as set forth in Subsection (2) of Section 167. If such a declaration of preclusion exists, the declaration of the person authorized to decide on disposal of the deposited embryo shall have precedence; in lieu of such a declaration the stipulations set forth for embryo donation shall be properly applied, and in doing so the healthcare provider at which the embryo was deposited shall be considered the healthcare provider making the donation.

(5) An embryo offered for donation shall be stored for a maximum of 5 years, which can be extended for one additional 5 year period. The maximum length of time during which a deposited embryo shall be stored is 10 years. An embryo that remains unused shall not be destroyed before expiration of the duration of the permitted storage period, unless it is probable that it is damaged. After expiration of the permitted storage period, the healthcare provider shall destroy the embryo or may use it for scientific research, precluding the

possibility that it may be used for reproductive purposes, or may transfer it to a research institute authorized to use it for such purposes.

Section 179

(1) It shall be the right of a child conceived and born as the result of donated reproductive cells and/or embryos to learn of the circumstances of his conception and birth upon reaching his majority, which shall include making available the data set forth in Subsections (2) - (3) of Section 172.

(2) The birth parent of the child, or immediately prior to the attainment of his majority, the legal guardian of the child shall be authorized to provide the information set forth in Subsection (1).

(3) When a child is conceived and born in accordance with Subsection (1) the persons requesting use of the reproductive cell or the reproduction procedure involving implantation of the embryo shall be considered the birth parents. An embryo conceived through in vitro fertilization shall be legally considered a viable fetus from the date of implantation.

(4) In the course of a procedure to determine the legal status of a child within the family, on request of an authority conducting proceedings, or of either of the members of the married couple (common-law couple) participating in the reproduction procedure, the healthcare provider performing the intervention shall certify to the fact of conducting the reproduction procedure and to its result.

Research, Investigations, and Interventions that May Be Conducted with Embryos and Reproductive Cells

Section 180

(1) Research with embryos or reproductive cells may be conducted on the basis of a permit issued by the Human Reproduction Committee as set forth in Section 186, in keeping with the order of documentation set forth in the permit and in accordance with the research plan approved simultaneously, by a healthcare provider or other research facility that has the professional conditions available to meet the objectives of the research.

(2) Embryos and reproductive cells shall be used for research, only for the research objectives set forth in Subsection (1) of Section 159.

(3) Embryos shall not be brought into existence for research purposes; research shall be conducted only on embryos brought about for reproductive purposes when this is authorized by the persons authorized to decide upon its disposal, or when the embryo is damaged.

(4) Human embryos shall not be implanted into the body of an animal, and human and animal reproductive cells shall not be used to fertilize one another.

(5) During reproductive procedures or other healthcare services, or during medical research, an embryo shall not be turned into multiple embryos or, with the exception of the provisions of Subsection (1) - (2) of Section 182, shall not be manipulated by changing its characteristics from those existing at the time of conception or by introducing new characteristics when the embryo is intended for viability; multiple individuals that conform to one another genetically shall not be brought about.

Section 181

(1) An embryo on which research has been conducted must not be implanted into the human body, and reproductive cells that have been used for research must not be used in

reproductive procedures. An embryo used for research shall be kept viable for a maximum of 14 days, not counting the time it was frozen for storage, even considering the duration of the research.

(2) Examinations for purposes of diagnostics or therapy, or to determine the suitability of an embryo for replanting or implanting, shall not qualify as embryo research for purposes of applying this Act.

Section 182

(1) Procedures to select the gender of progeny prior to birth may be conducted to identify heritable diseases linked to gender or to prevent the occurrence of said diseases.

(2) Various genetic specifics of an embryo may be altered, as opposed to the provisions of Subsection (1), to prevent or treat diseases expected to occur in the child that will be born, to the extent and in the manner considered absolutely necessary to achieve the purpose.

(3) Separation of the cells in an embryo only shall be done to diagnose diseases considered probable to occur in the child once born, and to determine damage to an embryo.

(4) The married couple (common-law couple) bringing about the embryo shall give a written statement of consent, after receiving proper information, prior to completing the procedures set forth in Subsections (1) - (3), which shall be executed by a healthcare provider authorized to conduct reproduction procedures.

Sections 183-184⁴⁵

Reducing the Number of Embryos or Fetuses in Multiple Pregnancies

Section 185

(1) When a multiple pregnancy exists, intrauterine intervention may be conducted when it is considered medically probable that certain embryos (fetuses) have development disorders rendering them non-viable or, while viable, have suffered damage resulting in serious and untreatable disabilities, to reduce the embryos (fetuses) carried to term to the healthy ones.

(2) In order to carry the pregnancy to term, to bring healthy children into the world, or to ensure a safe pregnancy that does not endanger the life and well-being of the embryos (fetuses) or the mother, the number of embryos (fetuses) in a multiple pregnancy can be reduced even when all embryos (fetuses) are healthy.

(3) In the case set forth under Subsection (1), on recommendation of the responsible genetic counselor, the number of intra-uterine fetuses can be reduced up until the 20th week of gestation, or, if the diagnostic process is prolonged, until the 24th week. With respect to a multiple pregnancy set forth under Subsection (2), on recommendation of a specialist physician, the number of fetuses can be reduced until the 12th week of gestation, or if there is an obstacle to diagnosing the multiple pregnancy at an earlier time, until the 14th week of gestation.

(4) In procedures to reduce the number of intra-uterine embryos (fetuses), the provisions of Act 79 of 1992 on Protection of Fetal Life (hereinafter: Fetal Protection Act) shall have precedence in issues not regulated by this Act. The provisions of this Act do not effect the

⁴⁵ Repealed together with the subtitle preceding Section 183, by Subsection (1), Section 32 of CXIX of 1999

opportunity to reduce the number of fetuses for other reasons set forth by the Fetal Protection Act as cause for premature termination of a pregnancy (abortion).

The Human Reproduction Committee

Section 186

- (1) The MRC's Human Reproduction Committee (hereinafter: Committee) shall operate as the Minister of Health's advisory, decision-making and supervisory body in the area of reproduction procedures and medical research conducted with embryos.
- (2) The Committee shall conduct the tasks set forth in this Act and by separate statute.
- (3) In particular, the tasks of the committee shall be to
 - a) provide preliminary opinions on granting operation licenses to healthcare providers to conduct reproduction procedures and/or so store reproductive cells (embryos) in frozen form, to continuously monitor operations, and when necessary to make recommendations on specific measures to be taken by the health service providers, the bodies maintaining them, and by the health authority responsible for professional supervision;
 - b) grant permits for medical research with embryos and/or reproductive cells, based on the research plan documentation presented to it;
 - c) render opinions of statutes and professional rules affecting reproduction processes, and to propose the establishment or amendment of statutes;
 - d) continuously evaluate domestic and international practices related to reproduction procedures, and to research with embryos.
- (4) In conducting the tasks set forth under Paragraph a) of Subsection (3), any member of the Committee shall be authorized to enter the premises of a healthcare provider being monitored, to access documentation on the various interventions, and to request additional information on the activity being studied.
- (5) One portion of the Committee members shall be appointed by the Minister of Health from among board-certified obstetricians/gynecologists with satisfactory experience in the profession, and from among persons with legal qualifications, while the other portion shall be delegated directly by social organizations and scientific bodies affected by the conduction of reproduction procedures.
- (6) The detailed rules governing the tasks, operation, and composition of the Committee shall be regulated by a Minister of Health Decree.

Sterilization

Section 187

- (1) Sterilization, which shall render either gender incapable of reproduction may be performed for purposes of family planning, or for medical reasons, based on a written application from the woman or man affected, on a satisfactory specialist medical opinion, or on recommendation of the latter.
- (2) Sterilization for purposes of family planning may be performed on a person over the age of 35 years, or a person who has three birth children of his own. To validate an application by the persons set forth in Subsections (1)-(2) of Section 16, the agreement of the public guardianship authority is necessary.

(3) Sterilization for purposes of family planning shall be performed only on Hungarian citizens with an address or place of residence in Hungary.

(4)⁴⁶ Sterilization may be performed only after three months have elapsed after the date on which the application was submitted, except when

a) a delivery or other surgical event makes it possible to complete the intervention as a priority case, or

b) a pregnancy that might occur in the interim would directly endanger the life, physical well-being or the health of the woman, or when it is highly probable that a child born of the pregnancy would not be healthy.

(5)⁴⁷ Prior to beginning the intervention, a physician appointed by the healthcare provider that will conduct the intervention shall provide information to the applicant, and if married or living in a common law marriage, to the spouse or common-law spouse as well, on other opportunities for contraception, as well as on the nature of the intervention, and the possible risks and consequences.

Chapter X

TREATMENT AND CARE OF PSYCHIATRIC PATIENTS

Section 188

For the purposes of this chapter

a) *psychiatric institute*: any institution providing healthcare, or one also providing healthcare, that offers services to, supervision of, and care for psychiatric patients 24 hours a day, irrespective of the other services provided by said institution, the body maintaining said institution, and the name by which it is known. In Sections 189-195, a psychiatric institute providing specialized outpatient care for psychiatric patients, a home for psychiatric patients, and a rehabilitation institute, including a transitioning institution and a facility providing community psychiatric services shall qualify as a psychiatric institute. Separate rules for homes and rehabilitation institutes for psychiatric patients shall be set forth under separate statute. A separate statute shall set forth the different rules governing bodies involved with involuntary commitment to treatment and/or transitional involuntary commitment to treatment ordered during the course of criminal proceedings and/or conducting psychiatric observation.

b) *dangerous behavior*: the patient, as a result of a disturbance in his psychotic condition, may pose a significant threat to his own or others' physical well-being or health, while the nature of the disorder does not warrant urgent institutional treatment;

c) *immediately dangerous behavior*: the patient, as a result of an acute psychotic condition, poses an immediate and serious threat to his own or others' life, physical well-being, or health.

Title I

Special Rules on the Rights of Psychiatric Patients

⁴⁶ Established by Subsection (1), Section 15, Act LXXI of 1999. In force as of 1 August 1999.

⁴⁷ Inserted by Subsection (2), Section 15, Act LXXI of 1999. In force as of 1 August 1999.

Section 189

- (1) Special protections shall be put into place to safeguard the rights of psychiatric patients receiving healthcare services, specifically because of their situation.
- (2) The rights of a psychiatric patient as set forth under Sections 6-21 shall be restricted, while receiving healthcare services, only in keeping with the specifications of this Act, and only to the degree and for the duration of time absolutely necessary, excepting the provisions of Section 193, and only if the patient's behavior qualifies as dangerous or immediately dangerous. However, the right to human dignity shall not be restricted, even in this case.

Section 190

Every psychiatric patient shall be entitled

- a) to undergo psychiatric treatment within his family and home environment whenever this is possible, and
- b) to be treated with the least restrictive method, causing the least discomfort, as suited to his conditions, while protecting the physical well-being of the other patients, and
- c) during the course of psychiatric treatment, the application of restrictive or coercive measures, or placement among restrictive conditions shall occur only in extremely justified cases, when the patient is a clear danger to self or others.

Section 191

- (1) General rules for consent (Sections 15-19) shall be applied in treatment of a psychiatric patient. In the case of a patient being treated under Paragraphs b) and c) of Section 196 as long as the patient displays dangerous or immediately dangerous behavior, patient consent shall not be mandatory, but even in cases such as this an attempt shall be made to inform the patient to the extent that this is possible.
- (2) Above and beyond the information provision generally required under Section 13, when a patient is admitted to a psychiatric institute he shall be informed orally and in writing of his rights, with particular respect to the essence of the court procedure and the rights of the patient in this respect.
- (3) After the dangerous or immediately dangerous behavior ceases, the patient shall be informed in detail, in accordance with general rules (Section 13).

Section 192

- (1) Only a patient who exhibits dangerous or immediately dangerous behavior shall be restricted in his personal freedom in any manner whatsoever. The restriction shall only be maintained, and shall only be employed to the extent and in the manner that is absolutely necessary to avert the danger.
- (2) Subsections (4) - (5) of Section 10 shall be applied in ordering restraints and in the mode of restriction. The physician shall immediately be notified of the restriction, and said physician shall have to approve the measure within 2 hours. If this is not forthcoming, the restriction shall be immediately discontinued.

Section 193

In the case of a psychiatric patient, said patient may be exceptionally restricted in his right to learn the contents of his healthcare documentation, if there is a well founded reason to assume that accessing this information would seriously jeopardize the patient's improvement, or if the personal rights of another individual would be infringed upon through said access to healthcare documentation. A physician shall be the only one authorized to order this restriction.

Section 194

- (1) When ordering the restrictions set forth in Sections 192-193, the patients' advocate and the legal or authorized representative of the patient shall be notified immediately.
- (2) The restrictions on patients' rights imposed shall be documented in detail and the reasons for them shall be expounded.

Section 195

- (1) A patient shall have a right to participate in work therapy, but may not be forced to participate in work therapy or to do any other work.
- (2) It shall be made possible for a patient to participate in the work of maintaining the institution if his condition can be expected to improve as a result.
- (3) The patient shall be remunerated for said work, in accordance with the provisions of the Minister of Health Decree.

Title 2

Institutional Treatment of Psychiatric Patients

Section 196

A psychiatric patient may be admitted to an institute for treatment

- a) with the agreement of the patient, or at the request of the person set forth in Subsections (1) - (2) of Section 16 (hereinafter: voluntary treatment),
- b) when displaying an immediately dangerous behavior requiring immediate institutional treatment, following measures taken by the physician assessing the behavior (hereinafter: emergency treatment),
- c) when a court issues a decision ordering mandatory institutional treatment (hereinafter: mandatory treatment).

Voluntary Treatment

Section 197

- (1) Treatment shall be considered voluntary when a patient in possession of full disposing capacities has given written consent prior to admission to a psychiatric institute.
- (2) A person with a limited disposing capacity or one whose disposing capacity is severely impaired may be admitted to a psychiatric institute for treatment at the request of the person set forth in Subsections (1) - (2) of Section 16.
- (3) A court shall investigate the need for the treatment and the validity of the consent
 - a) at the request of the patient in cases under Subsection (1), or when the admission was at the request of the person set forth in Subsections (1) - (2) of Section 16,
 - b) under Subsection (2), it shall investigate ex officio.
- (4) The person in charge of the psychiatric institute or ward (together, hereinafter: psychiatric institute) is mandated to immediately transfer the request set forth in Paragraph a) of Subsection (3) to the court, and to immediately notify the court of the admission in cases set forth under Paragraph b) of Subsection (3).
- (5) Within 72 hours of receipt of notification, the court shall investigate to determine whether the conditions of voluntary treatment are being met. Prior to rendering a decision, the court shall hear the patient, the person in charge of the institute or a physician delegated by that person, and shall procure the expert opinion of an independent forensic psychiatrist, who is not participating in treatment of the patient.
- (6) If the proceedings set forth in Subsections (3) - (5) find that treatment of the patient is not justified, the court shall order that the patient be discharged. In this case, the patient shall be discharged from the institute within 24 hours after the court has rendered its legally binding decision. If the statement of consent or the request serving as the basis for voluntary treatment are invalid, subject to the existence of the conditions defined in this Act, the court shall order mandatory institutional treatment of the patient.
- (7) A patient in full possession of disposing capacities shall be discharged from the institution at his request, and a patient whose disposing capacities are seriously impaired or who has limited disposing capacities shall be discharged at the request of the person initiating the admission.
- (8) A patient admitted voluntarily shall not be discharged if in the course of treatment he displays dangerous or immediately dangerous behavior and the need for institutional treatment exists for that reason. In this case the procedure regulated by Section 199 shall be conducted.

Section 198

- (1) In cases as set forth by Subsections (1) - (2) of Section 197, the court shall periodically review the need for institutional treatment. When the patient is in an inpatient institute for psychiatric treatment, the court shall review the case every thirty days, and when the patient is in a psychiatric rehabilitation institute it shall review the case once every sixty days.
- (2) Court review as set forth in Subsection (1) of Section 197 shall be conducted only if the patient does not object.

Emergency Treatment

Section 199

- (1) If a patient manifests immediately dangerous behavior because of a mental disorder or an addiction, and if the danger can be averted only by immediate admission to and treatment in a psychiatric institute, the physician observing this behavior shall take immediate measures to transport patient to the proper psychiatric institute. If necessary, police shall assist in transporting the patient.
- (2) Within 24 hours of admission of the patient, the person in charge of the psychiatric institute shall notify the court and initiate a court finding that there were grounds for the admission, and request a court order for mandatory treatment of said patient in a psychiatric institute.
- (3) The court shall issue a decision within 72 hours of notification. Until the court decision is rendered, the patient may be temporarily detained in the institute.
- (4) Before the decision is rendered, endeavors shall be focused on eliminating the acutely threatening behavior or on preventing a rapid deterioration in the patient's condition. To the extent that it is professionally possible, interventions making it impossible for the court to judge the mental condition of the patient during the course of a personal interview shall be avoided. When such interventions are applied, they shall be fully documented and the reasons shall be set forth.
- (5) The court shall order mandatory treatment for a patient admitted in an emergency if the patient exhibits dangerous behavior and the need for institutional treatment exists.
- (6) Prior to taking its decision the court shall hear the patient, the person in charge of the institution or the physician delegated by that person, and shall procure the expert opinion of an independent forensic psychiatrist, who is not participating in treatment of the patient.
- (7) When a patient is admitted in an emergency, the court proceedings shall be conducted even if the patient had consented to institutional treatment prior to the rendering of the court decision.
- (8) The court shall revisit the need for treatment every thirty days.
- (9) The patient shall be discharged from the psychiatric institute when there is no longer any justification for institutional treatment.

Mandatory Treatment

Section 200

- (1) The court shall order mandatory treatment of a patient in a psychiatric institute when said patient exhibits dangerous behavior because of a mental disorder or an addiction, but when there is no cause for emergency treatment.
- (2) The procedure for ordering mandatory treatment shall be initiated by the specialist physician in the psychiatric institute who determines the need by notifying the court, and shall recommend the psychiatric institute where the treatment is to occur.
- (3) The court shall render a decision on ordering mandatory institutional treatment within 15 days of receipt of notification.
- (4) Prior to rendering its decision the court shall hear the patient, the expert opinion of an independent forensic psychiatrist - who is not participating in treatment of the patient - who

has been subpoenaed to attend the hearing of the patient, and the specialist initiating the procedure.

(5) If the patient does not appear when subpoenaed, the court may order that he be brought before the court. Other coercive measures shall not be applied.

(6) If the court orders mandatory institutional treatment for the patient, and the patient does not appear at the psychiatric institute set forth in the order within three days of receipt of the legally binding decision, the physician initiating the proceedings shall act to have the patient brought in. When necessary, police shall participate in transport of the patient.

(7) The court shall periodically review the need for mandatory institutional treatment as set forth in Section 198.

(8) A patient ordered to submit to mandatory treatment shall be discharged from the institute when there is no longer cause for said treatment.

Common Rules of Procedure

Section 201

(1) The court shall conduct non-litigation proceedings in the proceedings set forth under this chapter. If this Act or the non-litigious nature of the proceedings do not suggest other conclusions, the rules set forth in Act 3 of 1952 on Court Proceedings and Civil Suits shall be applied as appropriate.

(2) The non-litigious proceedings regulated in this chapter shall be cost-exempt.

(3) The court local to the home or place of residence of the patient shall have jurisdiction in procedures ordering mandatory psychiatric treatment. The court local to the headquarters of the psychiatric institute shall have jurisdiction in proceedings to review the need for treatment in a psychiatric institute.

(4) Proper representation of the patient shall be ensured during court proceedings. When authorized by the patient or patient's legal representative, the patients' advocate shall have the right to represent the patient. If, in the course of the proceedings, the patient has no legal or authorized representative, the court shall assign a guardian ad litem.

(5) The patients' advocate or guardian ad litem representing the patient shall have to seek out the patient prior to the court hearing, to inform said patient of the circumstances of admission to the institution, and to inform patient of his rights as related to the proceedings.

(6) If necessary, the hearing may be conducted at a venue other than the courtroom.

(7)⁴⁸ During the hearing, the forensic psychiatric expert shall issue a statement regarding whether or not the patient is competent to manage his affairs.

(8) A decision taken in said proceedings may be appealed within 8 days of the announcement of said decision.

(9) An appeal of a decision for mandatory institutional treatment shall not delay execution of the decision when the need for emergency treatment has been determined.

(10)⁴⁹ When in the opinion of the forensic psychiatric expert the patient is not competent to manage his affairs because of reduced insight or an absence of insight, the court shall forward the expert opinion to the public guardianship authority with jurisdiction at the patient's place of residence, to initiate proceedings to appoint a guardian.

⁴⁸ Established by Subsection (1), Section 16, Act LXXI of 1999.

⁴⁹ Established by Subsection (2), Section 16, Act LXXI of 1999.

Chapter XI

ORGAN AND TISSUE TRANSPLANTATION

Section 202

For the purpose of this Chapter:

- a) *tissue*: any part of the human body with the exclusion of the following:
 - aa) sperm and ovum
 - ab) embryo and fetus
 - ac) blood and blood component;
- b) *organ*: any part of the human body composed of tissues of specialized structure, which, if removed entirely, cannot be renewed by the body,
- c) *organ and tissue transplantation*: the removal of an organ or a tissue from one person and its transplantation to another live person,
- d) *donor*: a person who donates an organ or tissue for grafting into another person's body, or one from whom an organ or tissue is taken, after his death, for grafting into another person's body,
- e) *recipient*: the person into whose body an organ or a tissue is transplanted that has been removed from another person's body,
- f) *brain death*: entire, permanent, and irreversible cessation of functions of the brain, including the brain stem,
- g) *death*: beginning of irreversible autolysis of the organism due to entire cessation of respiration, circulation and brain functions.

Section 203

- (1) Primarily organs and tissues removed from cadaver donors should be used for transplantation.
- (2) No advertising of human organs and tissues for any use whatsoever will be permitted.
- (3) Organ and tissue transplants from live or cadaver donors that are steadily storable and may be transplanted shall be stored in organ and tissue banks.
- (4) Transplantation and storage of organs and tissues shall only be undertaken in medical institutions authorized by the Minister of Health.
- (5) The Minister of Health shall stipulate the detailed regulations governing organ and tissue transplantation in a decree.⁵⁰

Removal of organs and tissues from live donors

Section 204

- (1) Organs and tissues removed from the body of live donors, with the exceptions as in Subsection (2), must be subjected to histopathological study.
- (2) No histopathological study shall be required if:
 - a) the removal is done for the purpose of transplantation into another person's body,

⁵⁰ Cf. Decree 18/1998 (XII.27.) EüM.

- b) the removal is done in order to perform a special diagnostic examination, and
- c) in the case of particular organs or tissues as specified by the decree of the Minister of Health.⁵¹

Section 205

- (1) Removal of transplants from a live donor for transplantation to another person shall be restricted to the following organs or tissues:
- a) one of a paired organ whose removal will not result in severe and permanent disability,
 - b) a part of an organ (organ segment) whose removal will not greatly alter physiological functions,
 - c) renewable tissues.
- (2) In case of Paragraph b) of Subsection (1) the regulations governing organ transplantation shall be applied.

Section 206

- (1) Organs and tissues, with the exception of Subsection (5), may only be donated by a person with legal capacity.
- (2) Donation of organs from a person with legal capacity shall be allowed only if the donor is:
- a) a lineal kin of the recipient,
 - b) a sibling of a lineal kin of the recipient,
 - c) a sibling of the recipient,
 - d) a lineal kin of a sibling of the recipient.
- (3) Donation of an organ may be possible in exceptional cases, when the stipulations as in Subsection (2) are not met. In this case the joint request of donor and recipient shall be considered by a hospital ethics committee. The hospital ethics committee shall give consent to the removal of the organ only after it has established that a close emotional relationship exists between the donor and the recipient, and the donation has taken place without consideration in return, force, duress, coercion or deception.
- (4) Detainees and conscripts may become organ donors only in cases as in Subsection (2).
- (5)⁵² Bone marrow, hematopoietic primordial cells or other renewable tissues might be taken for transplantation into a kin as in Subsection (2) even from the body of a person under legal age. In this case the consent of the legal representative will become valid after it has been endorsed by the hospital ethics committee. Prior to making its decision, the hospital ethics committee shall give the underage person a hearing and ascertain that the underage person has agreed to the intervention without force, duress, coercion or deception.

Section 207

- (1) Donation of organs and tissues shall only take place without consideration given in return.
- (2) The donors shall be eligible for recompense of loss of income related to the donation, and of his justified costs incurred in connection with making his statement of donation and with

⁵¹ Cf. Decree 18/1998 (XII.27.) EüM.

⁵² Amended by Paragraph a), Subsection (3), Section 24, Act LXXI of 1999

travelling, which are not reimbursed under his social insurance coverage. Such costs shall be borne by the state.

Section 208

Before a transplant procedure of an organ or tissue is undertaken, the physician to remove and transplant the organ or tissue must document that the donor meets the conditions for organ or tissue transplant, there is no medical contraindication of the transplant, furthermore that the transplant is justified for the recipient, the conditions for the procedure are met and that the organ is suitable for transplantation.

Section 209

(1) Before the removal of an organ or tissue is undertaken, the donor must be fully informed, verbally and in writing, and beyond the general rules as in Section 13, of all important circumstances related to the procedure, with special regard to the possible short-term and long-term consequences of organ or tissue removal, or the loss of an organ, and to the mandatory postmortem that must be performed on a donor after death. The information of the donor shall be done by a physician who is not involved directly in the transplantation procedure.

(2) The donor's consent to an organ donation shall be incorporated in a public deed. Such public deed must contain, beyond the general requirements of a consent, the donor's declaration stating that the donation has taken place without force, duress, coercion or deception and that he gives consent to autopsy following his death.

(3) The donor's consent to a tissue donation shall be incorporated in a private deed having full probative force.

(4) The donor is at liberty to withdraw his consent any time until the removal of the organ or tissue without any formal restrictions. Even in case of a valid consent the physician must terminate the organ or tissue donation procedure if during the course of such procedure a situation has arisen that will endanger the donor's life or impair his health.

(5) The recipient shall be informed of all significant circumstances in connection with the procedure, pursuant to the general rules (Section 13), and especially of the following:

- a) the risks for the donor's health involved in organ donation,
- b) the requirement of mandatory post-mortem after his death,
- c) the origin of the organ or tissue to be transplanted into his body .

(6) The consent of the recipient to the transplant must be committed to paper.

Section 210

If the donor sustains impairment to his health or bodily harm as a result of organ or tissue donation, excluding the harm inherent in the loss of an organ or tissue, becomes disabled or dies, and provided that it cannot be imputed to the healthcare worker carrying out the procedure, he or his dependent relatives shall be eligible to recompense by the state for all the damages that are not reimbursed under his social insurance coverage.

Removal of organs or tissues from cadaver donors

Section 211

- (1)⁵³ Organs or tissues may only be removed from cadaver donors if the deceased did not make a declaration opposing donation during his lifetime. A person with legal capacity may make a declaration in writing (in a public deed or private deed having full probative force), or verbally at his attending physician in case of inability to, or significant difficulty in making a written declaration. A person with restricted legal capacity may make an opposition declaration without his legal representative's involvement. Such opposition declaration may be made on behalf of a person with no legal capacity by his legal representative.
- (2)⁵³ The attending physician must establish within the time available for organ or tissue removal if an opposition declaration has been left by the deceased.
- (3)⁵³ If no written opposition declaration is found or forwarded to the attending physician within the time available for transplant removal, its absence should be presumed.
- (4) If the deceased is under age and no opposition declaration can be found, the organ or tissue removal procedure may be initiated only after the written consent of the legal representative of the deceased has been obtained.

Section 212

- (1) Organ or tissue removal may be commenced only after members of a committee of three physicians (hereinafter: committee) have determined brain death, by their independent and corroborating judgment, pursuant to the provisions in the decree of the Minister of Health.
- (2) The members of the committee shall be physicians who possess special medical knowledge and practice, have undergone special training and have been appointed by the head of the medical institution.
- (3) Physicians who are involved in organ or tissue removal or transplant, or in the treatment of the recipient shall not be members of the committee.
- (4) The committee shall place on record the results of clinical and instrumental investigations and the probable cause of death.
- (5) Once brain death is established, mechanical ventilation and artificial maintenance of other bodily functions shall only be justified if undertaken in order to maintain the functional capacity of organs or tissues for transplantation.

Section 213

Organs or tissues removed from the deceased but not transplanted shall be subjected to histopathological study.

Section 214

Organs or tissues may be removed for transplantation from victims of crimes, unless otherwise provided by separate piece of legislation and pursuant to the provisions as in Section 211, provided the prior written consent of the investigating authority has been obtained. In this case changes caused by the procedure must be documented in detail.

⁵³ Established by Section 17, Act LXXI of 1999. In force as of 1 August 1999

Organ or tissue implantation

Section 215

- (1) Patients in whose cases organ or tissue transplantation is medically justified shall be put on a national waiting list maintained separately by type of organ and tissue. Entry into the waiting list shall be initiated by the medical institution establishing indication for organ or tissue transplantation.
- (2) The patient shall be kept informed of all significant circumstances in connection with his name being put onto the waiting list.
- (3) Recipients shall be selected from the waiting list exclusively on the basis of professional rules.
- (4) The health authority shall exercise professional control over how individuals are put onto, and selected from the waiting list, and shall investigate patient complaints.

Chapter XII

PROVISIONS REGARDING THE DEAD

Section 216

For the purposes of this chapter:

- a)⁵⁴ *clinical death*: the transitional cessation of respiration, circulation or brain function, which shall not infer the onset of death or brain death;
- b)⁵⁴ *brain death*: the complete and irreversible cessation of brain functioning, including the functioning of the brain stem;
- c)⁵⁴ *death*: the condition in which the irreversible deterioration of the body begins as a result of the complete cessation of respiration, circulation and brain functioning;
- d)⁵⁵ *perinatal death*:
 - da) intrauterine death following the 24th week of gestation, or when the fetus is at least 30 cm or weighs at least 500 g at the time of intrauterine death,
 - db) when a neonate dies within 168 hours of delivery, irrespective of the length or weight of the neonate.

Section 217⁵⁶

- (1) The onset of death shall be determined through an inquest. Such inquest shall cover all circumstances necessary to determine
 - a) the de facto onset of death,
 - b) the circumstances of the death (natural causes or exceptional circumstances),
 - c) the cause of death.

⁵⁴ Cf. Subsection (3), Section 245

⁵⁵ Cf. Subsection (2), Section 245

⁵⁶ Established by Section 18, Act LXXI of 1999

(2) An ambulance officer or a physician as set forth under separate statute shall be authorized to determine the provision set forth under Paragraph a) of Subsection (1). Only a physician as set forth under separate statute shall be authorized to determine the provisions of Paragraphs b) - c) of Subsection (1).

(3) Only following a medical inquest that determines the de facto onset of death shall a deceased person, or fetus or neonate in the case of perinatal death, be transferred from the place where death occurred, for autopsy, burial, cremation, or organ or tissue harvesting.

(4) Rules governing inquest and medical procedures concerning the dead shall be set forth under separate statute.

Section 218

(1) In cases of death under exceptional circumstances, administrative proceedings shall be conducted, and a coroner's post mortem shall be ordered.

(2) The purpose of a coroner's post mortem shall be to clarify the cause and circumstances of death.

(3) A death qualifies as having occurred under exceptional circumstances if the circumstances under which it occurred make it doubtful that it would have occurred under natural conditions meaning that,

- a) the circumstances of occurrence suggest a felony,
- b) the death was caused or is suspected to have been caused by a traffic accident or occupational accident,
- c) the death was caused by another type of accident or poisoning, and it is necessary to investigate responsibility in relation to cause of death,
- d) the death was the result of suicide, or of conditions suggesting suicide,
- e) the death occurred during the course of healthcare treatment and there is a suspicion of employment rules infractions on the part of a healthcare worker,
- f) the factors and circumstances leading to the death are unknown, and there is no data available on which to form a well-founded assumption regarding the circumstances of the death,
- g) the death was that of a detained person.

(4) If the deceased person has not been identified, the procedure set forth for death under exceptional circumstances shall be followed until the person has been identified.

(5) Procedure to be followed in cases of death under exceptional circumstances, and regulations for a coroner's post mortem shall be set forth under separate statute.

Section 219

(1) The deceased person shall be subject to autopsy, irrespective of whether the death occurred in an inpatient healthcare facility or elsewhere, if

- a) clinical examinations were unable to determine the cause of death,
- b) perinatal death occurs,
- c) the deceased was a donor or recipient of a transplanted organ,
- d) the deceased had an occupational disease, and it is suspected that the illness contributed to the cause of death,

- e) a re-usable valuable instrument or implement, that was not the property of the deceased, was implanted in the body of the deceased person, unless the nature of the instrument or implement does not require that the deceased undergo an autopsy,
- f) the case is scientifically or educationally significant,
- g) intentions are to cremate the deceased, unless the provisions set forth in Subsection (3) shall apply,
- h) the person set forth in Subsections (1) - (2) of Section 16 requests it.

(2)⁵⁷ With the exception of the cases set forth in Subsection (1), an autopsy of the deceased does not have to be performed if all of the following conditions exist:

- a) the cause of death was natural
- b) the cause of death can be determined unambiguously,
- c) no further significant findings can be expected of an autopsy,
- d) when the death occurred in an inpatient healthcare facility and the attending physician and the pathologist deem it unnecessary, or when the death occurs elsewhere and the attending physician deems it unnecessary.

(3)⁵⁷ An autopsy need not be performed under the conditions as set forth in Subsection (2), if the deceased, while still alive, or a family member following the death, requested that no autopsy be performed, it need not be performed in the cases set forth in Paragraphs f) - g) of Subsection (1) either. An autopsy shall in all cases be performed if the deceased requested it in writing while still alive, or a family member submits a written request following the death.

(4) The medical director of an inpatient healthcare facility (university department) shall submit a written decision stating that an autopsy need not be performed when the person has died in said facility, while in other cases the health authority shall submit a written decision to that effect.

(5) The objective of an autopsy is to

- a) conduct a detailed examination of all pathological conditions existing prior to death, and to diagnose diseases,
- b) collect public morbidity and mortality data,
- c) monitor the effectiveness of the diagnostic and therapeutic procedures performed by healthcare services,
- d) promote the advance of medicine and pharmacology.

Section 220

(1) In the course of an autopsy or a coroner's post mortem, organs or tissue may be harvested

- a) to diagnose the disease underlying death, to determine immediate cause of death, and to determine the circumstances of the death,
- b) if the deceased issued no orders to the contrary while still alive, for purposes of education and research, other therapeutic utilization, and for transplant [Subsection (1) of Section 211].

(2) Organs or tissue may not be removed from the body of a person who died while in detention, unless the purpose is to determine the cause and circumstances of death, or if done for scientific reasons.

⁵⁷ Established by Section 19, Act LXXI of 1999.

(3) With the exception of transplants, the inpatient healthcare institute may request reimbursement for the costs of removing organs and tissues for other therapeutic purposes from the user of the organ or tissue.

(4) Following an autopsy or coroner's post mortem, the body shall be restored, out of respect for the dead.

Section 221

(1)⁵⁸The declaration set forth under Paragraph h) of Subsection (1) of Section 219 shall be in the form of an official document or a private document with full evidentiary validity.

(2) The person issuing the declaration may be exempted from the formal requirements set forth in Subsection (1) if said person is in an inpatient healthcare institution and would incur significant difficulty in providing a written declaration. In this case, an oral statement, spoken before two concurrently present witnesses may be issued, and shall be set into written form by the inpatient healthcare facility.

Section 222

(1) Medical interventions on a body may be conducted to educate medical undergraduates if the deceased issued no orders to the contrary while still alive. The intervention shall not interfere with ascertainment of the cause of death or with restoration of the body out of respect for the dead.

(2) The body of a deceased person may be transferred to a school of medicine to be used for instruction in anatomy if, while still alive, the person

a) specifically agreed to this , or

b) did not object to it and the person responsible for his burial, should there be such a person, agrees to this in writing within 30 days of the death.

(3) The transfer shall be free-of-charge.

Chapter XIII

BLOOD SUPPLY

Section 223

(1) Blood supply shall be understood as a healthcare and social activity aimed at ensuring blood and blood products needed for therapy and blood products, and at the use of blood products for therapeutic purposes.

(2) The scope of this Act does not extend to blood products procurable in retail pharmacies.

(3) Defining the system of conditions for supplying blood, ensuring the existence of said conditions, and organization and safe and uniform operation of the blood supply system shall be a state task.

(4) To ensure safe use of blood products, efforts shall be made for national self-sufficiency with blood and blood products.

⁵⁸ Amended by Paragraph e), Subsection (2), Section 24, Act LXXI of 1999.

(5) Tasks related to the blood supply shall be conducted and/or monitored by the central and regional units of state organizational systems operating in accordance with the uniform professional principles and requirements of the National Blood Supply Service.

(6) A Minister of Health Decree shall set forth the rules for the organization and operation of the National Blood Supply Service.

Section 224

Blood and blood products, unless otherwise set forth by statute, shall not be commercially distributed.

Section 225

(1) Within the scope of providing blood and blood products required for therapy, the blood supply service shall be tasked with

- a) assessing needs,
- b) organizing blood donation drives in cooperation with the Hungarian Red Cross and other social organizations,
- c) the examination of blood donors,
- d) drawing the blood to produce therapeutic products,
- e) producing or procuring the blood products, and examining them.
- f) storing and registering the blood products,
- g) inventorying the blood products,
- h) monitoring the blood products,
- i) distributing the blood products,
- j) destroying blood and blood products when they are no longer safe to use.

(2) Within the scope of the therapeutic use of blood products, the blood supply service shall be tasked with

- a) performing a serological examination on a patient in need of a blood product and choosing the proper product for said patient as evidenced by the serological examination,
- b) participating in healthcare activity related to administering the blood product to the patient, examining the body's reaction to the product administered, and collecting and evaluating related data.

Section 226

(1) When organizing blood donation drives, voluntary donors shall be sought and, with the exception of the cases set forth under separate statute, no remuneration shall be provided.

(2) The blood donor, to protect his own health and the health of the patient receiving the product made from the donated blood, shall be examined to determine his fitness to donate blood. As part of said examination, donor shall provide information on his own state of health and on his lifestyle, if it should have any significance from the point of view of infectious diseases that may be transmitted through blood, at the request of the physician performing the examination.

(3) A blood donor shall be entitled to special recognition from society, as set forth under separate statute.

(4) If a donor is injured or dies as a result of blood donated in keeping with professional rules, he or his dependants shall receive compensation from the state.

Section 227

(1) A patient shall be provided with the quality and quantity of blood products professionally justified by the state of his health.

(2) Hungarian citizens are entitled to the service set forth under Subsection (1) free of charge.

(3) Non Hungarian citizens shall be required to pay for the blood received, unless otherwise provided by law. In emergencies, the ability to pay shall be determined only after the blood has been received.

(4) If a patient is injured or dies in connection with receiving a blood product provided in accordance with professional rules, he or his dependants shall receive compensation from the state.

Chapter XIV

DISASTER MEDICAL CARE

Section 228

(1) In the event of disasters, health care for patients shall be delivered within the frameworks of disaster medical care.

(2) For the purposes of this law, disaster shall mean an incident of a usually sudden occurrence that endangers, or disrupts, the lives, corporal integrity and health of citizens, or the functioning of health care providers to such magnitude that leads to disproportion between the demand for health care and the locally available capabilities, furthermore that calls for the collaboration of health authorities, healthcare providers as well as other central and local government agencies, regardless if such incident occurs during a qualified period (state of emergency, state of distress, contingency) or beyond it.

(3) Beyond a qualified period, an incident may be declared a disaster

- a) by the chief medical officer, if it affects a county (capital city),
- b) by the Minister of Health, if it affects more than one county.

Section 229

(1) In the event of a disaster, patients' rights as defined in this Act shall be exercised exclusively and to such an extent, if and when they do not endanger the effectiveness of disaster response and relief. Notwithstanding, the right of patients to human dignity must not be restricted.

(2)⁵⁹ In the event of a disaster, regulations concerning the healthcare delivery system, the professional requirements of health services as well as the rights and obligations of health care workers shall be applied with the deviations as provided for in this Chapter, furthermore

⁵⁹ Established by Section 20, Act LXXI of 1999. In force as of 1 August 1999.

with the deviations as provided for by a piece of legislation enacted based on the authorization provided in this Chapter.

(3) In the event of a disaster, the Minister of Health, or the health authority, shall be entitled to draft in any healthcare worker to practice health care activity in another locality of the country, with the exception of workers in the healthcare facilities of the defence, police and law-enforcement authorities.

Section 230

(1) It shall be a state responsibility to arrange for and fund the provision of disaster medical care.

(2) The obligation of the state to arrange for disaster medical care includes the organisation for and implementation of disaster medical services.

(3) Preparation for the provision of disaster medical services shall include:

- a) planning activities,
- b) determination of the order of control and command,
- c) determination of the order of co-operation between sectors and regions,
- d) development of legal and administrative regulations,
- e) stocking health and medical supplies,
- f) delivering special training activities, and
- g) implementation of disaster medical care exercises.

(4) The operation of disaster medical care shall include :

- a) introduction of legal provisions that are in force exclusively in the event of a disaster,
- b) transformation of the organisation and operation of healthcare delivery system to the necessary extent,
- c) introduction of the order of control and command required for disaster response and relief,
- d) health care of patients,
- e) operation of emergency healthcare facilities, and
- f) drawing in additional capacities and stocks.

(5)⁶⁰ The costs of healthcare providers involved in the delivery of disaster medical assistance that are beyond the costs covered by the Health Insurance Fund shall be reimbursed by the central budget.

Section 231

(1) Supplies and materials required for delivering disaster medical assistance which exceed the stocks of healthcare providers and collaborating agencies shall be made available from the National Health Reserve.

(2) In the event that the National Health Reserve is exhausted during a disaster, arrangements shall be made for its supplementary re-supply to the necessary extent. In this case procurement of supplies and materials shall not be governed by public procurement regulations.

⁶⁰ Amended by Paragraph f), Subsection (2), Section 24, Act LXXI of 1999.

Section 232

- (1) The Minister of Health shall ensure that health legislation to take effect in the event of a specific disaster is available in a format that is suitable for promulgation.
- (2)⁶¹ The health care facilities designated by the Minister of Health shall be obliged to draw up disaster plans as part of their preparation. The criteria of contents of these disaster plans shall be defined by the Minister of Health.

Chapter XV**MEDICAL EXPERT SERVICES****Section 233**

- (1) For the purposes of this chapter, medical expert services, with the exception of the provisions of Subsection (2), shall involve provision of an expert opinion rendered by ascertaining facts and other circumstances that require medical expertise and a professional judgment of same.
- (2) Services provided by experts in forensic medicine, and the operations of experts in forensic medicine are governed by separate statute.

Section 234

- (1) Medical expert services, with the exceptions of the provisions set forth in Section 106 and Subsection (2) of Section 235, may be provided by a natural person who, unless otherwise provided by law, has been granted a license in accordance with the conditions set forth by the Minister of Health under separate statute.
- (2) Statutes may establish exclusive jurisdictions and authorities for the performance of specific medical expert services.

Section 235

- (1) A medical expert shall provide services upon being called upon to provide them, upon tasked with an assignment by statute, or upon receiving a commission to provide services.
- (2) If a medical expert is called upon by the police, prosecutorial authorities or court he shall be obliged to comply. He shall only be exempted from this obligation on his request, in cases set forth by statute.

Section 236

- (1) A medical expert may not provide an expert opinion on a case in which he or an immediate family member is involved or on any other case in which he cannot be expected to render an objective opinion (prejudice).
- (2) The medical expert shall immediately report the reason for being recused to the body calling upon him or commissioning her/him.

⁶¹ Amended by Paragraph h), Subsection (3), section 24, Act LXXI of 1999.

Section 237

- (1) When providing expert services and evolving an expert opinion, the expert shall act independently, and no instructions shall be given to him regarding matters of expertise.
- (2) In the course of providing medical expert services, procedure shall comply with professional rules in such a manner that the life, or physical or emotional well-being of the person affected by the expert investigation shall not be put at risk, and said person shall be subjected to the smallest possible travail.
- (3) Unless otherwise set forth by statute, the rules of healthcare services shall apply, as appropriate, to services provided by medical experts.
- (4) When providing medical expert services, patient rights shall be limited only in cases set forth by statute.
- (5) Other than the information he must reveal when rendering an expert opinion, all data and facts learned by a medical expert in any way in the course of his activity shall be considered confidential for unlimited duration.

Chapter XVI

NATURAL THERAPEUTIC REMEDIES. SPAS AND CLIMATE THERAPY INSTITUTIONS, HEALTH RESORTS

Natural Therapeutic Remedies

Section 238

- (1) Natural therapeutic remedies are defined as natural mineral water, natural mud, and other natural materials extracted from the soil (together, hereinafter: natural therapeutic remedies extracted from the soil), the surface climate, and underground climate (together, hereinafter: climatic therapeutic remedies) which have been proven to have favorable biological effects or which can be used for therapy.
- (2) Natural therapeutic remedies which have been granted permits to call themselves
 - a) natural mineral water,
 - b) natural therapeutic water,
 - c) natural therapeutic mud,
 - d) therapeutic climates
 - e) therapeutic caves or
 - f) by any other term suggesting a therapeutic effect
 are recognized natural therapeutic remedies.
- (3) Only those natural therapeutic remedies recognized by the authority set forth by the Minister of Health Decree (hereinafter: authority) shall be used for therapeutic purposes.
- (4) Natural therapeutic remedies extracted from the soil shall be commercially distributed only when granted a permit set forth under separate statute.

Section 239

The authority shall exercise the right of a specialized authority to provide an expert opinion on the quantity, quality and health service utilization of recognized natural mineral waters, therapeutic waters, therapeutic muds, and other natural remedies extracted from the soil, in proceedings involving the granting of permits, which shall include proceedings related to the issuance of operation licenses to health service providers or service providers partially involved in healthcare that operate using the natural therapeutic remedies.

Spas and Climate Therapy Institutions**Section 240**

A spa and climate therapy institution is a health service provider or a service provider which in part offers healthcare services using natural therapeutic remedies, which has been granted an operation license under conditions set forth under separate statute to use a name suggesting a spa or a climate therapy institution.

Therapeutic Locale**Section 241**

- (1) The term, therapeutic locale, shall be used only by a settlement (or part thereof) which possesses recognized natural therapeutic remedies, and which has received a permit from the authority authorized by a Minister of Health statute to grant said permits, in keeping with other conditions set forth under separate statute.
- (2) A protective zone may be demarcated to protect the natural therapeutic remedies of the therapeutic locale.

**Amending and Repealing Permits for Therapeutic Remedies, Spas,
Climate Therapy Institutions and Therapeutic Locales****Section 242**

All permits and agreements related to therapeutic remedies, spas, climate therapy institutions, and therapeutic locals may be amended or repealed on health and medical grounds, and maintenance of the permits or agreements may be linked to requirements to take measures for reasons of healthcare.

Chapter XVII**INTERNATIONAL PROVISIONS****Section 243**

- (1) Healthcare for non-Hungarian citizens within the borders of the Republic of Hungary shall be provided in accordance with valid international agreements or on the basis of

reciprocity. In the absence of said agreement or reciprocity, a non-citizen shall have access to healthcare as set forth by statute.

(2) The provisions of this Act on damages shall be applicable to non-citizens if a valid international agreement exists or if reciprocity is in effect.

(3) A non-citizen in need of emergency care within the borders of the Republic of Hungary shall receive immediate treatment. A non-citizen requiring medical intervention within the borders of the Republic of Hungary shall have access to said intervention under the same conditions as a Hungarian citizen.

(4) Removing blood, other tissue, or organs from the body of a non-citizen, or transplanting organs or tissue harvested from a Hungarian citizen or the body of a Hungarian citizen into the body of a non-citizen, shall occur in accordance with the provisions for Hungarian citizens.

(5) When a non-citizen dies within the borders of the Republic of Hungary

a) an autopsy shall be performed at the request of a member of the immediate family of the deceased,

b) a coroner's post mortem shall be performed if the death occurred under exceptional circumstances.

In the course of these autopsies, organs and tissues shall be removed only to determine the cause and circumstances of death.

(6)⁶² Organs and tissue shall be transported⁶² from the Republic of Hungary to another country or from another country to the Republic of Hungary only

a) for transplant,

b) for treatment of the patient transporting the organ or tissue,

c) for diagnostic purposes or

d) for research

if this is made possible by an international agreement or covenant. Another condition for transporting an organ to another country under Paragraph a), is that there shall be no suitable recipient within the borders of the Republic of Hungary.

(7)⁶³ The prerequisite for the validity of a contract concerning the transport of organs or tissue, other than blood and blood products, to another country or from another country to Hungary, other than when said contract is in the form of an interstate or intergovernmental agreement or covenant, is the agreement of the Executive Office of the Chief Medical Officer. The CMO's Executive Office shall deny its agreement if it can be determined that the contract involves profiting. There is no legal recourse against a decision of the CMO's Executive Office through government administration channels, but it may be challenged through the courts. The CMO's Executive Office shall keep a registry of said contracts or agreements, other than interstate or intergovernmental agreements or covenants, which shall be reported to it by the Hungarian party to said contracts or agreements.

(8)⁶⁴ When a non-Hungarian citizen dies, the consul of the nation of which the deceased is a citizen shall be notified immediately.

⁶² Established by Subsection (1), Section 21, Act LXXI of 1999. In force as of 1 August 1999

⁶³ Inserted by Subsection (2), Section 21, Act LXXI of 1999. In force as of 1 August 1999. For its application, cf. Subsection (1), Section 24 of the same law.

⁶⁴ Numbering modified by Subsection (2), Section 21, Act LXXI of 1999.

(9)⁶⁵ When a disaster occurs in another nation, participation in the provision of healthcare services or international epidemiological cooperation shall occur in keeping with international agreements or on the basis of reciprocity.

Chapter XVIII

CONCLUDING PROVISIONS

Section 244⁶⁶

With respect to claims for damages arising in relationship to healthcare services and/or measures taken by the authorities after the this Act enters into force, the regulations set forth in Act 4 of 1959 on the Civil Code of the Republic of Hungary shall be applied as appropriate.

Section 245⁶⁷

(1) This Act, with the exceptions set forth in Subsections (2) - (4), shall enter into force on the first day of the seventh month following its promulgation.

(2) Section 142, and Paragraph d) of Section 216 shall enter into force on January 1, 1998.

(3) Subsections (2) - (5) of Section 9, Subsection (1) of Section 114, Section 117, Sections 119-122, Section 124, Sections 148-149, Section 156, Sections 202-210, Sections 212-215, Paragraphs a) - c) of Section 216, Sections 217-222, and Sections 228-232 of this Act shall enter into force on January 1, 1999.

(4) Sections 30-34, Paragraph e) of Subsection (1) of Section 166, and Sections 183-184 of this Act shall enter into force on January 1, 2000.

(5) The registries of physicians, dentists and pharmacists to be established pursuant to Sections 111-113 of this Act shall be established on January 1, 2000 at latest.

Section 246

(1) When this Act enters into force

a)⁶⁸ Act 2 of 1972 on Health (hereinafter: Health Act) Sections 1-49, Subsection (5) of Section 52, Sections 59-63, Sections 67-69, and Sections 71-91 shall simultaneously become invalid, with the constraint that the provisions set forth in Subsection (2) of Section 53, Subsections (2) - (3) of Section 58 and the rules set forth in Section 22 shall continue to be applicable;

b)⁶⁸ amendments to the Health Act set forth in Act 57 of 1989, Act 87 of 1994, except Subsection (3) of Section 2; Act 22 of 1990, Sections 30-31, and Sections 34-35; Act 68 of 1990, Section 4; Act 9 of 1992, Sections 41-42; Act 33 of 1992, Paragraph a) of Subsection

⁶⁵ Numbering modified by Subsection (2), Section 21, Act LXXI of 1999

⁶⁶ Established by Section 22, Act LXXI of 1999. In force as of 1 August 1999.

⁶⁷ Text established with effect from the day of its entering into force, i.e. as of 1 July 1998, by Section 1, Act XXXVII of 1998.

⁶⁸ Text established with effect from the day of its entering into force, i.e. as of 1 July 1998, by Subsection (1), Section 2, Act XXXVII of 1998.

(1) of Section 83; Act 51 of 1994, Section 39; Act 66 of 1996, Sections 11-12, and Law Decree No. 6/1987, with the exceptions of Sections 7-8, and Sections 9-10, shall simultaneously become invalid;

c) Act 20 of 1991 on Local Governments and their Bodies, on Bodies Commissioned by the Republic, and on the Tasks and Jurisdictions of Certain Central Subordinate Bodies, Subsections (1) and (3) of Section 129, Paragraph 1) of Section 135, Section 136, and Act 90 of 1995, Paragraph b) of Subsection (2) of Section 27 shall simultaneously become invalid.

(2)⁶⁹ The Health Act Sections 50-54, with the exception of Subsection (5) of Section 52; Act 86 of 1994 amending the Health Act, Subsection (3) of Section 2, Law Decree No. 6/1987, Sections 7-8, and 10-11, shall become invalid on January 1, 1999. The Health Act, Section 70, and Subsection (4) of Section 245 shall become invalid at the time the registries are set up, but on January 1, 2000 at latest.

(3)

a)⁷⁰

b)⁷¹

c)⁷²

d)⁷³

Section 247

(1) The Government shall be authorized to

a) elaborate the detailed rules governing refusal of care,⁷⁴

b) set the general rules for beginning to provide and for providing healthcare services, and the rules governing procedures related to the granting of operation licenses,

c) set the detailed rules governing the tasks, organization, and operation of the National Healthcare Council,⁷⁵

d) set the rules governing management of the national inventory of blood, in particular, as related to importing and exporting blood products,⁷⁶

e) set the detailed rules of disaster health services⁷⁷

in the form of decrees.

(2) The Minister of Health shall be authorized to issue Decrees determining

a) the detailed rules governing waiting lists,⁷⁸

b) the detailed rules governing the legal status and procedures of the patients' advocate,⁷⁹

c) in agreement with the Ministers of Education and of Social and Family Affairs, the detailed rules governing the professional content of health education, and in agreement with

⁶⁹ Text established with effect from the day of its entering into force, i.e. as of 1 July 1998, by Subsection (2), Section 2, Act XXXVII of 1998.

⁷⁰ Incorporated: Paragraphs c)-d), Section 36, Act 4 of 1952

⁷¹ Incorporated: Subsection (1), Section 38, Act 4 of 1952

⁷² Incorporated: Subsection (3), Section 40, Act 4 of 1952

⁷³ Incorporated: Subsection (1), Section 43, Act 4 of 1952

⁷⁴ Cf. Government Decree 115/1998 (VI.16.) Korm.

⁷⁵ Cf. Government Decree 229/1998. (XII.30.) Korm.;

⁷⁶ Cf. Government Decree 115/1998. (VI. 16.) Korm; Government Decree 114/2000 (VI.29.) Korm.

⁷⁷ Cf. Government Decree 158/1999. (XI.19.) Korm.

⁷⁸ Cf. Minister of Health Decree 22/1998 (XII.27.)EüM

⁷⁹ Cf. Minister of Health Decree 77/1999. (XII.29.)EüM

the responsible Minister, the detailed rules governing the professional content of certain public health services,

- d) the detailed rules of certain public health thresholds, particularly as regards healthcare thresholds, and the detailed rules of certain epidemiological measures,⁸⁰
- e) the detailed rules regarding the order of patient referrals,
- f) the detailed rules of the various healthcare services,⁸¹
- g) the detailed professional rules for beginning to provide and for providing healthcare services and for the liability insurance of the health service providers, as well as the rules specifying the objective conditions required to provide healthcare services,⁸²
- h) the detailed rules on the basic registry of persons with professional healthcare qualifications, and on the operational registry of healthcare workers,⁸³
- i) the detailed rules governing professional education in health, higher level professional education, and continuing education in health, and the recognition or naturalization of basic, post-basic and higher-level professional education, as well as professional qualifications earned through higher level professional training and specialist professional training completed in other countries,⁸⁴
- j) the detailed rules governing the organization and operation of the Council of Professional Qualification and Continuing Education in Health,⁸⁵
- k) the detailed rules on the professional content of the quality system, and on the certification of compliance,⁸⁶
- l) the detailed rules governing the code of practice of healthcare workers,
- m) the detailed rules governing the tasks, organization, and operation of the Medical Research Council, the professional colleges, and the national institutes of health,⁸⁷
- n) the detailed rules on the organization and operation of the hospital supervisory boards and hospital ethics committees,⁸⁸
- o) the detailed rules governing medical research involving human subjects,
- p) the detailed rules governing special procedures related to human reproduction, and on the donation and frozen storage of reproductive cells and embryos, as well as on research conducted on reproductive cells and embryos,⁸⁹
- q) the detailed rules governing organ and tissue transplants, and on organ and tissue storage,⁹⁰
- r) the detailed rules governing the organization of blood donation drives, the cases in which remuneration may be provided for blood donations, the cost reimbursements blood donors shall be entitled to, and the rules of targeted blood donations (autologous blood donations, or donations for another specific individual),⁹¹

⁸⁰ Cf. Decrees 33/1998 (VI.24.)NM, 53/1999. (XI.12.)EüM, 61/1999 (XII.1.)EüM

⁸¹ Cf. Decrees 19/1998 (VI.3.)NM; 20/1998 (VI.3.)NM; 25/1998 (VI.17.)Nm; 47/1999 (X.6.)EüM; 53/1999 (XI.12.)EüM; 4/2000 (II.25.)EüM

⁸² Cf. Decrees 19/1998 (VI.3.)NM; 20/1998 (VI.3.)NM

⁸³ Cf. Decrees 27/1998 (VI.17.)NM; 30/1999 (VII.16.)EüM

⁸⁴ Cf. Decrees 28/1998 (VI.17.)NM; 11/1998 (XII.11.)EüM; 66/1999 (XII.25.)EüM; 72/1999 (XII.25.)EüM; 73/1999 (XII.25.)EüM

⁸⁵ Cf. Decrees 140/1998 (XII.11.)EüM

⁸⁶ Cf. Decree 47/1999 (X.6.)EüM

⁸⁷ Cf. Decree Decrees 14/1998 (IN.22.)NM; 52/1999 (XI.12.)EüM; 62/1999 (XII.7.)EüM

⁸⁸ Cf. Decrees 14/1998 (XII.11.)EüM; 23/1998 (XII.27.)EüM

⁸⁹ Cf. Decrees 25/1998 (VI.17.)NM; 30/1998 (VI.24.)NM

⁹⁰ Cf. Decree 18/1998 (XII.27.)EüM

⁹¹ Cf. Decree 43/1999 (IX.30.)EüM

- s) the rules governing the drawing of blood to produce a therapeutic blood product, and the manner of producing, storing, registering, inventorying, destroying, monitoring, distributing and issuing blood products,⁹¹
 - t) the detailed rules of the therapeutic utilization of blood products,⁹²
 - u) the detailed rules governing the organization and operation of the National Blood Supply Service,⁹³
 - v) the detailed rules governing the organization and operation of the National Ambulance and Emergency Service,
 - w) the detailed rules of managing the National Health Reserve, and
 - x) the detailed rules governing natural therapeutic remedies.⁹⁴
- (3) The Minister of Justice and the Minister of the Interior are hereby authorized to set the rules governing the healthcare of detained persons, in agreement with the Minister of Health.

⁹² Cf. Decrees 24/1998 (XII.27.)EüM; 43/1999 (IX.30.)EüM

⁹³ Cf. Decrees 26/1998 (VI.17.)NM; 44/1999 (IX.30.)EüM

⁹⁴ Cf. Decree 74/1999. (XII.25.)EüM