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Act No. 183/2017 Coll.	1.7.2017
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373

ACT

of 6 November 2011

on specific health services

The Parliament has passed the following Act of the Czech Republic:

Chapter I

General Provisions (Sections 1-2)

Basic provisions

Section 1

This Act

- a) regulates the provision of specific health services and related performance of state administration, the rights and obligations of patients and providers of health services (hereinafter referred to as the "Provider") and the rights and obligations of other legal and natural persons in connection with the provision of specific health services,
- b) incorporates the relevant European Union regulations¹, lays down general principles for the radiation protection of persons in connection with medical exposure, the implementation of radiological procedures and activities involving medical exposure and the level of responsibility of Providers and health professionals in relation to these procedures and activities, and lays down measures to ensure safety and health at work.

Section 2

- (1) Specific health services are health services provided under this Act.
- (2) The provisions of the Act on Specific Health Services shall apply in connection with the provision of specific health services unless otherwise provided in this Act.

CHAPTER II

Health services

provided under special conditions (Sections 3-32)

Part 1

Assisted reproduction (Sections 3-11)

Section 3

- (1) Assisted reproduction means methods and procedures for harvesting germ cells, manipulating them, creating a human embryo by fertilizing sperm eggs outside the body of a woman, manipulation with human embryos, including their storage, for the purpose of the artificial insemination of a woman
 - a) for medical reasons in the treatment of her infertility or male infertility, if
 1. it is unlikely or completely excluded that the woman can naturally conceive or carry a viable fetus, and
 2. other ways of treating infertility or infertility have not lead to or their is a high degree of probability that they will not lead to her becoming pregnant, or
 - b) with regard to the need for early genetic testing of the human embryo, if the health of the future child is at risk due to the demonstrable risk of transmission of the genetically-mediated diseases or defects which the woman or man is a carrier of.
- (2) Germ cells are defined for the purpose of assisted reproduction as eggs and sperm.
- (3) Artificial insemination of a woman is understood as
 - a) the introduction of sperm into the female sex organs, or
 - b) the transfer of a human embryo resulting from the fertilization of the egg by sperm outside the female body into the female sex organs.
- (4) For the artificial insemination of a woman, it is possible to use

- a) eggs obtained from this woman²,
 - b) sperm obtained from a male² who undergoes treatment of infertility together with the woman,
 - c) germ cells donated by a person² other than those referred to in a) and b) (hereinafter referred to as "Anonymous Donor"); an anonymous donor may only be a woman who has reached the age of 18 and has not passed the age of 35, or a male who has reached the age of 18 and has not passed the age of 40 years.
- (5) Germ cells and human embryos can only be used for artificial insemination. This does not apply in the case of human embryos not used for artificial insemination, which can be used for research on human stem embryonic cells, under the conditions and for the purposes established by the act governing human embryonic stem cell research³.

Section 4

Treatment with assisted reproductive methods may only be performed by a Provider who has been granted authorization to provide health services in the field of reproductive medicine.

Section 5

- (1) Assisted reproduction methods and procedures can be performed if the requirements of the Human Tissue and Cells Act² have been met.
- (2) The use of assisted reproduction methods and procedures is not permitted for the purpose of choosing the gender of the future child, with the exception of cases in which the use of assisted reproductive methods and procedures can help avoid serious genetically-mediated diseases related to gender.

Section 6

- (1) Artificial insemination can be performed on a woman of childbearing age if her age has not exceeded 49 years, based on a written request from a woman and man who intend to undertake this health service together (hereinafter referred to as the "Infertile Couple"). The application of an Infertile Couple requesting artificial insemination must not be older than 6 months; it forms part of the woman's medical documentation.
- (2) Artificial insemination cannot be carried out on a woman who is related to the man with whom she submitted the application under paragraph 1 in a way that excludes marriage under another legal regulation.

Section 7

- (1) Germ cells can be removed and used for assisted reproduction methods and procedures if medical fitness has been assessed
 - a) of the persons from whom the germ cells are to be taken, and
 - b) of the woman who is to be inseminated (hereinafter referred to as the "Recipient").
- (2) The Recipient must not be a person deprived of legal capacity or a person with limited legal capacity so that she is unable to assess the provision of health services, the consequences of their provision, or deprived of parental responsibility, even in part. The Recipient may also not be a person placed in a police cell, custody, imprisoned or detained.
- (3) The Anonymous Donor must not be a person
 - a) deprived of legal capacity or a person with limited legal capacity so that he/she is not competent to assess the provision of health services or the consequences of their provision,
 - b) placed in a police cell, custody, imprisoned or detained.
 - c) who has been ordered to be placed in isolation, quarantine or is in inpatient protective protective care, or
 - d) who has been hospitalized without consent.

Section 8

- (1) Prior to initiating assisted reproductive techniques and procedures, the Provider is required to inform the infertile couple about the nature of the proposed methods and procedures, their lasting effects and possible risks, and the manner in which surplus human embryos will be handled, including the estimated cost of their storage and the time of their storage. An Infertile Couple may require that a witness of their choice be present when the information is submitted. The record of the submission of information shall be signed by the Infertile Couple, the attending physician, or the witness; the record forms part of the medical records kept on the Recipient.
- (2) Based on the information provided in paragraph 1, the Infertile Couple shall give written consent to assisted reproduction; written consent must be given repeatedly before each artificial insemination. The consent forms part of the medical records kept on the Recipient.
- (3) The individual assisted reproduction procedures can be performed on the Recipient if she has granted consent prior to their commencement. The consent shall be recorded in the medical records kept on the Recipient by the attending physician, who shall sign the record; the record shall also be signed by the Recipient.

Section 9

- (1) If all human embryos created for the benefit of a Infertile Couple have not been used in the artificial insemination of the Recipient, they can be retained and used for further artificial insemination of the Recipient. This is not the case if the Infertile Couple states in writing that they do not intend to use these embryos for their further artificial insemination, and at the same time they consent to their use for another anonymous infertile couple or they consent to the use of surplus embryos for the research of human embryonic stem cells, or to their disposal. The statement may be revoked by the Infertile Couple at any time; this does not apply if the human embryo was used in another infertile couple or was disposed of in accordance with the statement. A human embryo derived from a Recipient's egg or sperm of the man in the Infertile Couple can be used for the artificial insemination of another recipient if the medical fitness of the Infertile Couple has been assessed to the extent specified for anonymous donors.
- (2) If the human embryos have not been used or the Infertile Couple has not made a written statement of their disposal pursuant to paragraph 1, the Provider may repeatedly demonstrably call upon the Infertile Couple in writing about the further retention of these embryos, including consent to their disposal, after 10 years of retaining these embryos. If the Infertile Couple does not respond to the repeated demonstrably sent written calls of the Provider, the human embryos can be discarded without a statement from the Infertile Couple.
- (3) A repeated written call under paragraph 2 shall be understood as demonstrably sent through the postal operator to the address of the Infertile Couple known to the Provider, at least twice, a minimum of 60 days apart. The deadline for the Infertile Couple's statement regarding the second call is 30 days from the date of delivery.
- (4) The call is delivered on the date on which the addressee accepts it, otherwise it is deemed to have been delivered within 10 days of the date of notification of its deposit with the postal service provider. If the call remains undelivered due to a change of address of the Infertile Couple or its acceptance was refused, the call is deemed to have been received on the date of its return to the Provider. The procedure is the same if the call is not delivered to only one person from the Infertile Couple.
- (5) On the basis of the written statement referred to in paragraph 1 or the written consent made on the basis of the call referred to in paragraph 2, the Provider shall ensure that the frozen human embryos are stored in the presence of at least two healthcare professionals. The medical records kept on the Recipient include a written statement or written consent, or a receipt or other document certifying the demonstrable sending of a written request to the Infertile Couple, and a record of the disposal of the human embryos; the record will be signed by the healthcare workers who were present during the disposal of the human embryos.

Section 10

- (1) The Provider, who is authorized to perform assisted reproduction methods and procedures, is required to ensure the mutual anonymity of the Anonymous Donor and the Infertile Couple and the anonymity of the Anonymous Donor and the child born from assisted reproduction.

- (2) The Provider, who has performed an assessment of the medical fitness of an Anonymous Donor and a woman or man from an Infertile Couple, is obliged to submit data on their health condition necessary for the artificial insemination to the provider who performs the artificial insemination; this provider is obliged to keep the data on the health condition of the Anonymous Donor for 30 years after the artificial insemination and, upon written request, submit information about the health condition of the Anonymous Donor to the Infertile Couple or to the adult person born from assisted reproduction.

Section 11

The person from whom the germ cells have been collected is not entitled to financial or other reimbursement. On the basis of a request, the Provider who performed the collection shall reimburse the Anonymous Donor's expenses expeditiously, cost-effectively and demonstrably incurred from the donation of germ cells. He/she may claim reimbursement from the Recipient to be inseminated, or the Provider to whom the germ cells or human embryos for assisted reproduction were submitted. The provider who accepted the germ cells or human embryos for performing assisted reproduction and who paid the expenses under the second sentence may claim reimbursement of that expenditure from the Recipient to be inseminated.

Part 2

Sterilization (Sections 12-16)

Section 12

Sterilization is a medical procedure that prevents fertility without removing or damaging the sexual glands. Sterilization can be performed for medical or non-medical reasons. Medical reasons is understood as those diseases or defects that have a high probability of being a serious threat to health or life due to pregnancy or childbirth, or to the healthy development of the fetus, or the health or life of the future child.

Section 13

- (1) Sterilization for medical reasons is performed on a patient who has reached the age of 18 years if he/she gives written consent to the sterilization.
- (2) In the case of a patient deprived of legal capacity, a patient with limited legal capacity in such a way that he/she is not competent to assess the provision of healthcare services or the consequences of their provision (hereinafter referred to as a "patient deprived of legal capacity"), or in the case of a minor patient, only sterilization for medical reasons can be performed, on the basis of
 - a) the written consent of his/her legal representative (hereinafter the "the patient's legal representative"); this is without prejudice to the provisions of Section 35 of the Health Services Act,

- b) a positive opinion of the expert committee and
 - c) the consent of the Provider's locally competent court.
- (3) The expert committee is established by the Provider. The members of the expert committee are
- a) 3 physicians with competence in the field of surgery or urology, in the case of sterilization in a man,
 - b) 3 physicians with competence in the field of gynecology and obstetrics, in the case of sterilization in a woman,
 - c) a clinical psychologist and
 - d) a person designated by a Provider who has obtained a university degree in a Master's program in the field of law (hereinafter referred to as a "lawyer").
- (4) At least 4 members of the expert committee must not be in a labor-law or similar relationship with the Provider, must not be members of the supervisory body of the Provider or a statutory body, members of a statutory body or partner of the Provider.
- (5) The attending physician of the patient who recommended the medical procedure may be invited to the meeting of the expert committee, however, the attending physician should not be present during the discussion of the members of the committee with the patient.
- (6) The patient and the patient's legal representative are always invited to a meeting of the expert committee; the committee's meeting must be initiated in such a way so as not to endanger the life or health of the patient. The expert committee submits to the patient and his/her legal representative information on the nature of the medical procedure, its lasting effects and possible risks, and verifies whether the patient and the patient's legal representative have fully understood this information. The patient's intellectual maturity shall be taken into account. A record of the submission of information shall be signed by the members of the expert committee, the patient, and the legal representative of the patient. The record includes the patient's opinion. If the patient is unable to understand or sign the information due to his/her intellectual maturity, this fact shall be included in the record. The record forms part of the patient's medical records.
- (7) After consulting the request, the expert committee will draw up a written expert opinion in which it will assess whether all the conditions for sterilization have been met; it shall also indicate the period of validity of the opinion, taking into account the urgency of carrying out the medical procedure. A positive opinion on sterilization requires the approval of all members of the expert committee. In the event that an agreement of all the members is not reached, the expert committee will describe the reasons which led to this situation. The Provider will submit a copy of the expert committee's opinion to the patient's legal representative.
- (8) The proposal for consent to sterilization is submitted to the court by the Provider. The Provider will attach the written consent of the patient's legal representative, the patient's opinion and the opinion of the expert committee to the proposal. If the patient is not able to make a statement

due to his/her intellectual maturity, the Provider shall state this fact along with its justification in the proposal.

Section 14

Sterilization for non-medical reasons may be performed on a patient who has reached the age of 21 years, unless serious medical reasons prevent from doing so, on the basis of his/her written request. The request forms part of the patient's medical records.

Section 15

- (1) Prior to performing sterilization for medical or non-medical reasons, the attending physician is required to provide the patient with information about the nature of the healthcare procedure, its lasting effects and possible risks. The information must be provided in the presence of a witness who is a healthcare worker. If the patient requests the presence of another witness of his/her choice, the Provider will allow for this. The record of the submission of information shall be signed by the attending physician, the patient, and the witness or witnesses; the record forms part of the medical records kept on the patient. There must be a reasonable time gap between the submission of information and the granting of consent; in the case of sterilization for health reasons, the period must be at least 7 days; in the case of sterilization for reasons other than health, the period must be at least 14 days.
- (2) The performance of the sterilization can be initiated if the patient or the legal representative of the patient has given his/her written consent immediately prior to the start of the procedure.

Section 16

Sterilization cannot be carried out in medical facilities of the Prison Service of the Czech Republic (hereinafter referred to as the "Prison Service").

Part 3

Therapeutic castration, testicular pulpectomy (Sections 17-20)

Section 17

- (1) Therapeutic castration or testicular pulpectomy (hereinafter referred to as Castration) is defined as a medical procedure that removes the hormonally active part of the male sex glands in order to suppress a man's sexuality.
- (2) Castration can be performed on a 25-year-old patient who has previously committed a violent sexually motivated crime if an expert medical examination has demonstrated the existence of

specific sexual deviations and a high probability of committing a violent sexually motivated crime in the future, and no other treatment methods were successful.

- (3) Castration is performed on a patient on the basis of
 - a) his written request and
 - b) a positive opinion of the expert committee.
- (4) A patient who is in protective treatment or security detention shall be castrated only in particularly justified cases and on the basis of
 - a) his written request,
 - b) a positive opinion of the expert committee and
 - c) the consent of the Provider's locally competent court.

Section 18

- (1) The expert committee is established by the Ministry of Health (hereinafter referred to as the "Ministry"). The members of the expert committee are
 - a) a healthcare worker who is an employee of the state assigned to the Ministry,
 - b) a physician with competence in the field of sexology,
 - c) a physician with competence in the field of psychiatry,
 - d) a clinical psychologist,
 - e) a physician with competence in the field of urology,
 - f) a lawyer with knowledge of health law.
- (2) A member of the expert committee must not be in a labor-law or similar relationship with the Provider, must not be a member of the supervisory body of the Provider or a statutory body, a member of a statutory body or partner of the Provider.
- (3) The patient's request shall be immediately forwarded by the Provider to the Ministry; the request shall be accompanied by an assent regarding the performance of Castration of the attending physician with competence in the field of sexology, and an independent medical opinion demonstrating a high probability that the patient will commit a violent sexually motivated crime in the future. The assent shall include a diagnosis and description of the treatment to date. The Ministry may request a copy of the Criminal Records Register in order to verify the fulfillment of the condition of committing an offense under Section 17 (2); the request

for a copy of the Criminal Records Register and the copy of the Criminal Records Register shall be handed over in electronic form in a manner allowing for remote access.

- (4) The patient is always invited to the meeting of the expert committee, which shall be held no later than 3 months after the date of the patient's request. The expert committee submits to the patient the information regarding the nature of the medical procedure, its lasting effects and possible risks, and verifies whether the patient has fully understood this information and whether he chose to submit the request voluntarily. A patient who is in protective treatment or security detention will be informed that Castration does not entitle him to release.
- (5) The record on the submission of the information shall be signed by the members of the expert committee and the patient.
- (6) After consulting the request, the expert committee will draw up a written expert opinion in which it will assess whether all the conditions for Castration have been met; it shall also indicate the period of validity of the opinion, taking into account the urgency of carrying out the medical procedure. A positive opinion on sterilization requires the approval of all members of the expert committee. In the event that an agreement of all the members is not reached, the expert committee will describe the reasons which led to this situation. The expert committee shall submit to the Ministry 3 copies of the expert opinion and one copy of the minutes of the meeting.
- (7) The attending physician of the patient who recommended the medical procedure may be invited to the meeting of the expert committee, however, the attending physician should not be present during the discussion of the members of the committee with the patient.
- (8) The patient's medical records include
 - a) a written request from the patient,
 - b) a copy of the assent of the attending physician with competence in the field of sexology,
 - c) an independent medical opinion pursuant to paragraph 3,
 - d) the minutes of the meetings of the expert committee and
 - e) the opinion of the expert committee.
- (9) The Ministry shall submit
 - a) a copy of the opinion of the expert committee and a copy of the minutes of the meeting of the expert committee to the patient,
 - b) 2 copies of the opinion of the expert committee to the Provider to be documented in the medical records pursuant to paragraph 8, and for submission to the court pursuant to paragraph 10, and a copy of the minutes of the meetings of the expert committee.

- (10) The proposal for consent to castration is submitted to the court by the Provider. The Provider will attach the written request of the patient and the opinion of the expert committee to the proposal.

Section 19

The performance of castration can be initiated if the patient has given his written consent immediately prior to the commencement of the procedure.

Section 20

Castration cannot be carried out in medical facilities of the Prison Service and on persons in custody and imprisonment. Castration can neither be performed on a patient deprived of legal capacity.

Part 4

Changing the sex of transsexual patients (Sections 21-23)

Section 21

- (1) For the purposes of this Act, changing the sex of transsexual patients is understood to mean the execution of medical procedures with the purpose of changing sex via surgical intervention while simultaneously disabling reproductive function. A transsexual patient means a person who has a persistent incongruity between his/her mental and physical sex (hereafter "gender identity disorder").
- (2) Surgical procedures aimed at sex change can be performed on a patient
- a) who has been clearly identified as having a gender identity disorder and has demonstrated the ability to live permanently as a person of the opposite sex, and
 - b) who has not entered into a registered partnership or a similar same sex relationship abroad, or who can demonstrate that his/her marriage or registered partnership or similar relationship no longer exists.
- (3) Surgical procedures aimed at sex change are performed on a patient aged 18 years and older, on the basis of
- a) his written request and
 - b) a positive opinion of the expert committee.
- (4) Surgical procedures aimed at sex change are performed on a patient deprived of legal capacity on the basis of

- a) the written consent of his/her legal representative; this is without prejudice to the provisions of Section 35 of the Health Services Act,
 - b) a positive opinion of the expert committee and
 - c) the consent of the Provider's locally competent court.
- (5) A sex change cannot be performed on a patient in custody, imprisonment, detention or protective treatment.

Section 22

- (1) The expert committee is set up by the Ministry. The members of the expert committee are
- a) a healthcare worker who is an employee of the state assigned to the Ministry,
 - b) a physician with competence in the field of sexology,
 - c) a physician with competence in the field of psychiatry,
 - d) a clinical psychologist,
 - e) a physician with competence in the field of diabetes and endocrinology,
 - f) a physician with competence in the field of urology or gynecology and obstetrics,
 - g) a lawyer with knowledge of health law.
- (2) A member of the expert committee must not be in a labor-law or similar relationship with the Provider, must not be a member of the supervisory body of the Provider or a statutory body, a member of a statutory body or partner of the Provider.
- (3) The request of the patient or the patient's legal representative shall be forwarded by the Provider to the Ministry without delay; it shall attach the assent to the attending physician with competence in the field of sexology regarding gender sex reassignment.
- (4) The patient is always invited to a meeting of the expert committee, which is held no later than 3 months after the date of the patient's request. The expert committee submits to the patient and his/her legal representative information on the nature of the medical procedure, its lasting effects and possible risks, and verifies whether the patient and the patient's legal representative have fully understood this information and whether the patient and his legal representative chose to submit the request voluntarily. In the case of a patient referred to in Section 21 (4), his intellectual maturity shall be taken into account.
- (5) A record of the submission of information shall be signed by the members of the expert committee, the patient, and the legal representative of the patient. The opinion of the patient

deprived of legal capacity also forms part of the record. If the patient is unable to understand or sign the information due to his intellectual maturity, this fact shall be included in the record.

- (6) After consulting the request, the expert committee will draw up a written expert opinion in which it will assess whether all the conditions for sex change have been met; it shall also indicate the period of validity of the opinion, taking into account the urgency of carrying out the medical procedure. A positive opinion on sterilization requires the approval of all members of the expert committee. In the event that an agreement of all the members is not reached, the expert committee will describe the reasons which led to this situation. The expert committee shall submit to the Ministry 3 copies of the expert opinion and one copy of the minutes of the meeting.
- (7) The attending physician of the patient who recommended the medical procedure may be invited to the meeting of the expert committee, however, the attending physician may not be present during the discussion of the members of the committee with the patient.
- (8) The patient's medical records include
 - a) a written request from the patient or the patient's legal representative,
 - b) a copy of the assent of the attending physician with competence in the field of sexology,
 - c) the minutes of the meetings of the expert committee and
 - d) the opinion of the expert committee.
- (9) The Ministry shall submit
 - a) a copy of the opinion of the expert committee and a copy of the minutes of the meeting of the expert committee meeting to the patient or legal representative,
 - b) 2 copies of the opinion of the expert committee to the Provider to be documented in the medical records pursuant to paragraph 8, and for submission to the court pursuant to paragraph 10, and a copy of the minutes of the meetings of the expert committee.
- (10) The proposal for consent to sex change is submitted to the court by the Provider. The Provider shall attach to the proposal the written request of the patient or the written request of the patient's legal representative, the statement of the patient deprived of legal capacity, and the opinion of the expert committee. If the patient is not able to make a statement due to his/her intellectual maturity, the Provider shall state this fact along with its justification in the proposal.

Section 23

- (1) The performance of sex change can be initiated if the patient has given his/her written consent immediately prior to the commencement of the procedure.
- (2) The Provider will issue the patient a confirmation of the sex change.

Part 5

Psycho-surgical procedures (Sections 24-27)

Section 24

- (1) Psycho-surgery is understood to mean neurosurgery performed to eliminate or alleviate the symptoms of mental illness when other treatment methods have already been exhausted and there is a high probability that the procedure will be effective.
- (2) Psycho-surgery is performed on a patient who has reached 18 years of age, on the basis of
 - a) the written consent of the patient and
 - b) a positive opinion of the expert committee.
- (3) In the case of a patient aged 18 and over who is in custody, imprisonment, detention or protective treatment, psycho-surgery is performed only in particularly justified cases, on the basis of
 - a) his written consent,
 - b) a positive opinion of the expert committee and
 - c) the consent of the Provider's locally competent court.
- (4) In a minor patient or a patient deprived of legal capacity, psycho-surgery is performed only in particularly justified cases, on the basis of
 - a) the written consent of his/her legal representative; this is without prejudice to the provisions of Section 35 of the Health Services Act,
 - b) a positive opinion of the expert committee and
 - c) the consent of the Provider's locally competent court.

Section 25

- (1) The expert committee is set up by the Ministry. The members of the expert committee are
 - a) a healthcare worker who is an employee of the state assigned to the Ministry,
 - b) a physician with competence in the field of psychiatry,
 - c) a physician with competence in the field of neurology,

- d) a physician with competence in the field of neurosurgery,
 - e) a clinical psychologist,
 - f) a lawyer with knowledge of health law.
- (2) A member of the expert committee must not be in a labor-law or similar relationship with the Provider, must not be a member of the supervisory body of the Provider or a statutory body, a member of a statutory body or partner of the Provider.
- (3) The consent of the patient or the patient's legal representative shall be given by the Provider to the Ministry without delay; this consent must be supplemented with the consent of the attending physician with competence in the field of psychiatry with the performance of the psycho-surgical procedure.
- (4) The patient is always invited to a meeting of the expert committee, which is held no later than 3 months after the date of the patient's request. The expert committee submits to the patient and his/her legal representative information on the nature of the medical procedure, its lasting effects and possible risks, and verifies whether the patient and the patient's legal representative have fully understood this information. In the case of a patient referred to in Section 24 (4), his/her intellectual maturity shall be taken into account.
- (5) A record of the submission of information shall be signed by the members of the expert committee, the patient, and the legal representative of the patient. The opinion of a minor patient or a patient deprived of legal capacity also forms part of the record. If the patient is unable to understand or sign the information due to his intellectual maturity, this fact shall be included in the record.
- (6) After discussing the request, the expert committee will draw up a written expert opinion in which it will assess whether all the conditions for the performance of the psycho-surgical procedure have been met; it shall also indicate the period of validity of the opinion, taking into account the urgency of carrying out the medical procedure. A positive opinion on sterilization requires the approval of all members of the expert committee. In the event that an agreement of all the members is not reached, the expert committee will describe the reasons which led to this situation. The expert committee shall submit to the Ministry 3 copies of the expert opinion and one copy of the minutes of the meeting.
- (7) The attending physician of the patient who recommended the medical procedure may be invited to the meeting of the expert committee, however, the attending physician may not be present during the discussion of the members of the committee with the patient.
- (8) The patient's medical records include
- a) written consent of the patient or legal representative of the patient,
 - b) a copy of a assent of the attending physician with competence in the field of psychiatry,

- c) the minutes of the meetings of the expert committee and
 - d) the opinion of the expert committee.
- (9) The Ministry shall submit
- a) a copy of the opinion of the expert committee and a copy of the minutes of the meeting of the expert committee meeting to the patient or legal representative,
 - b) 2 copies of the opinion of the expert committee to the Provider to be documented in the medical records pursuant to paragraph 8, and for submission to the court pursuant to paragraph 10, and a copy of the minutes of the meetings of the expert committee.
- (10) The proposal for consent to the psycho-surgical procedure is submitted to the court by the Provider. The Provider will attach the written consent of the patient or the written consent of the legal representative, the statement of a minor patient or a patient deprived of legal capacity, and the opinion of the expert committee. If the patient is not able to make a statement due to his/her intellectual maturity, the Provider shall state this fact along with its justification in the proposal.

Section 26

The performance of the psycho-surgical procedure can be initiated if the patient or the legal representative of the patient has given his/her written consent immediately prior to the start of the procedure.

Section 27

Psychosurgical procedures cannot be performed in medical facilities of the Prison Service.

Part 6

Genetic testing (Sections 28-30)

Section 28

- (1) Genetic testing includes clinical and laboratory testing; its purpose is to determine the proportion of variants in the human germline genome in the development of the disease in a patient. Genetic laboratory testing means the laboratory analysis of the human germline genome or parts thereof.
- (2) Genetic laboratory testing may only be performed in laboratories whose competence has been assessed in accordance with the relevant harmonized standard⁵ by the accrediting person⁶.

- (3) Genetic health testing can only be offered or performed for the purposes of
- a) health services, that is,
 - 1. pre-implantation diagnosis in assisted reproduction,
 - 2. diagnosing genetically-engineered diseases and developmental defects,
 - 3. determining the rate of predisposition to diseases and developmental defects,
 - 4. determining the unmarked transfer of variants of the human germline genome that cause diseases or developmental defects,
 - 5. targeted screening of newborns for the detection of genetically-mediated diseases; for the purpose of genetic testing, targeted screening means detecting the proportion of changes in the human germline genome on the development of serious genetically-mediated diseases with the risk of early irreversible damage to the health of newborns,
 - 6. optimizing treatment,
 - b) biomedical research related to health and its disorders.
- (4) Genetic testing can only be offered or performed on a patient
- a) after informing about its purpose, nature and impact on health, including the health of future generations, and on the risks of unexpected findings for the patient and the genetically related person; and
 - b) on the basis of his or her written consent or the written consent of the patient's legal representative.
- (5) For the purposes of genetic testing under this Act, genetically related persons to the patient are relatives with a medically serious genetic risk, namely
- a) direct relatives, such as grandparents, parents and their children, and
 - b) indirect relatives, where the degree of this risk is determined by the degree of affinity and type of genetic disease.
- (6) In the event that the genetic testing results in a diagnostic conclusion that can be expected to have an impact on the health of the patient, including future generations, or on the health of genetically related persons, the Provider shall recommend to the patient and to the genetically related person the provision of genetic counseling by a physician with a specialized competence in the field of medical genetics, both prior to and after the examination.

Section 29

- (1) Genetic laboratory testing of biological material taken from a deceased person's body for educational, scientific and research purposes can only be carried out under the condition that a person close to the deceased has given demonstrable consent or the deceased gave demonstrable consent during his/her lifetime. If the deceased banned the provision of information regarding his/her health condition during his/her lifetime, the testing cannot be performed; this does not apply if it is necessary to ascertain or verify important information about changes in the human germline genome of the deceased to ensure the health of genetically related persons.
- (2) The patient may not be offered or provided any financial compensation or other benefit for undergoing genetic testing pursuant to Section 28 (3) a). The rejection of the genetic examination must not be detrimental to the patient and he/she must not be subjected to psychological pressure. The results of genetic testing must not be provided to third parties without the patient's written consent. The sale or donation of the results of genetic testing to third parties without the written consent of the patient, including the written consent of the genetically related person concerned, is prohibited. The results of the genetic testing must not be used for any discrimination against the patient and the genetically related person.
- (3) Genetic laboratory testing of a human embryo or fetus, including the determination of its sex, may not be performed for reasons other than the purposes under Article 28 (3) (a) points 1 to 3 and point 6. Laboratory genetic testing of a human embryo or fetus may be performed provided that a physician with specialized competence in the field of medical genetics provides genetic counseling to a mother, which is followed by genetic counseling for the proper interpretation of the results after the termination of the laboratory genetic examination of a human embryo or fetus. Laboratory genetic testing of a human embryo or fetus shall be performed only after the information has been submitted and with the written consent of the mother (Section 28 (4)).

Section 30

- (1) An intervention aimed at transforming the human germline genome may be performed in patients for preventive or therapeutic purposes only in the case of serious genetically-mediated diseases, under the condition that its natural biological integrity in germ cells is maintained. These interventions should not be performed if they could lead to changes in the germ cell genetic makeup.
- (2) Any process whose purpose is to create a human being that has the same human genome as another human being, whether alive or dead, is prohibited.
- (3) It is forbidden to transfer
 - a) the entire human genome into cells of another animal species and vice versa,
 - b) the human embryo into the reproductive organs of another animal species.

Part 7

Sampling of human blood and its components, treatment with blood or its components (Sections 31-32)

Section 31

Sampling of human blood and its components

- (1) The sampling of human blood and its components (hereinafter referred to as "blood") for the production of transfusion products and blood derivatives and for use on humans may be carried out only by a provider authorized to do so under the Medicines Act.
- (2) Blood for the purposes referred to in paragraph 1 cannot be sampled from
 - a) minors; this does not apply in cases where the sampling of blood from the minor cannot be replaced by sampling blood from an adult; in such a case, the written consent to the blood sampling must be provided by the legal representative of the minor, and the sampling must be approved by the authorized healthcare worker of the provider referred to in paragraph 1,
 - b) persons who are in a police cell, custody, imprisonment or detention
 - c) persons placed in a school facility for the exercise of constitutional care or protective education or in a social service facility, if institutional care was ordered, or protective education was imposed,
 - d) persons in prescribed isolation, quarantine or inpatient protective protective care, or
 - e) persons hospitalized without their consent.

The prohibition of blood sampling under points (b) to (e) shall not apply to direct donation between direct relatives, which cannot be replaced by taking blood from another person, and for sampling needed to perform healthcare services to the person from whom the blood is being sampled, such as auto-transfusion.

- (3) Blood for the purposes referred to in paragraph 1 may only be drawn from a person who has provided written consent. In the case of a person who is a minor or deprived of his/her legal capacity, written consent is granted by his/her legal representative; this is without prejudice to Section 35 of the Health Services Act.

Section 32

Treatment with blood or its components

- (1) Treatment with blood means administering transfusion products to a patient by transfusion, and blood derivatives and other medicinal products derived from human blood to a patient in the

context of preventive or curative care. Prior to the administration of the transfusion product via transfusion, the compatibility of the transfusion product with the blood of the recipient is assessed. The provider is responsible for assessing the compatibility of the transfusion product with the blood of the recipient. A record of the compatibility of the transfusion product with the patient's blood is part of the patient's medical documentation; the record shall be signed by the healthcare worker who verified the compatibility of the blood transfusion product with the recipient's blood.

- (2) Blood sampled for the production of blood derivatives and for human use under other legislation does not entitle the person from whom the blood has been sampled to financial or other reimbursement, except for expeditiously, cost-effectively and demonstrably incurred expenses, which the person requests, up to a maximum of 5% of the minimum wage.
- (3) The provider may reasonably increase the reimbursement of expenses determined in accordance with paragraph 2 regarding blood sampling
 - a) for the purpose of producing an individual blood transfusion product for the provision of healthcare to a particular patient, and if blood from another donor cannot be used,
 - b) requiring special donor preparation or donor selection based on the tissue and blood groups of the recipient.

Chapter III

Verifying new procedures

using a method that has not yet been introduced

into clinical practice

on a living person (Sections 33-40)

Section 33

- (1) In the case of living persons, verification of new procedures in the field of preventive, diagnostic and medical care or biomedical research related to health and its disorders can be carried out using a method not yet introduced into clinical practice (hereinafter referred to as the "non-established method"), only under the conditions laid down by this Act .
- (2) The following are not considered non-established methods:
 - a) methods introduced into clinical practice in a Member State of the European Union, the European Economic Area or the Swiss Confederation,

- b) modifications of already established methods, the use of which does not have adverse effects on the patient's health.
- (3) In case of doubt whether the method in one referred to in paragraph 2 (b), the Ministry shall decide, either by official authority or at the request of a provider who intends to use the modification of methods used in the provision of health services. The filing of a dissolution against the decision of the Ministry has no suspensive effect. The participants in the procedure are only the providers who intend to use the modification of the already introduced methods for the provision of health services.
- (4) The verification of a non-established method can only be performed if
- a) the patient on whom the non-established method is to be verified has granted, on the basis of the information referred to in Article 34 (1), written consent to the verification of the non-established method,
 - b) it can be expected that the non-established method will yield favorable results for the benefit of the patient on whom it is to be verified, and it can be reasonably assumed that, after successful verification, it will become a new method of prevention, diagnosis or treatment,
 - c) verification of the non-established method cannot be achieved with comparable effectiveness in a different way, and
 - d) there is no reasonable risk that the verification of the non-established method will result in long-term or serious damage to the health of the patient on whom the non-established method is to be verified.
- (5) Verification of a non-established method may be performed on a minor patient or patient deprived of legal capacity only on the basis of the written consent of the patient's legal representative after providing them the information pursuant to Section 34, if
- a) the conditions set out in paragraph 4 b) to d) are fulfilled,
 - b) verification of the non-established method cannot be performed with comparable efficacy on patients who are able to consent, and
 - c) these patients, with regard to their intellectual maturity or their ability to understand information, have provided their consent to the verification; disagreement of patients and with the verification need not be respected if such verification is the only possible treatment alternative for an otherwise untreatable disease;
- this is without prejudice to Section 35 of the Health Services Act.
- (6) Verification of non-established methods cannot be performed on persons in custody, imprisonment or security detention, unless such verification is the only possible treatment alternative for an otherwise untreatable illness.

Section 34

- (1) Information about the non-established method submitted to the patient or legal representative of the patient on whom the method is to be verified must be demonstrable and comprehensible and include
- a) data on the verified method, including the purpose for which it is verified,
 - b) the specific procedure that will apply to the patient,
 - c) the possible benefit of the verified method for the patient,
 - d) the foreseeable risks and possible difficulties or limitations associated with the verification of the method, and the foreseeable risks associated with the premature withdrawal of consent,
 - e) data on other treatment options,
 - f) information on the protection of the data collected about the patient and on the manner of disclosing information and data identified in connection with the verification of the method relevant for the evaluation and implementation of the verified method; and
 - g) cooperation requirements and the patient's treatment regimen;
- this is without prejudice to Section 35 of the Health Services Act.
- (2) The consent of the patient or the patient's legal representative to the verification of the non-established method must be valid throughout the verification period. In the case of the withdrawal of consent by the patient or the patient's legal representative, the method verification cannot be continued.

Section 35

Verification of a non-established method can be performed by a provider to whom the Ministry has given permission to verify the non-established method. In addition to the requirements set forth by the Administrative Code, the request for permission shall include

- a) description of the non-established method,
- b) the rationale for the effectiveness of the verification of the non-established method,
- c) a report on the results obtained by laboratory research, animal experiments or other pre-clinical research,
- d) an overview of current knowledge about the verified practices, including findings from abroad,
- e) a detailed plan of the verification of the non-established method,

- f) the place where the non-established method is to be verified, indicating the name, or names, and surname(s) of the healthcare workers who will verify it, including the names of those who will manage the verification, and their qualifications,
- g) an assessment of health risks, taking into account all available information on the method, that might arise when verifying the non-established method,
- h) informative data on the circle of patients on which the non-established method is to be verified,
- i) a binding opinion of the State Office for Nuclear Safety on the verification of a non-established method with medical irradiation, for which radiation exposure is intended to have a direct health benefit on the persons subjected to it, or which is being verified as part of biomedical research related to health and its disorders.

Section 36

- (1) The Ministry will grant the provider permission to verify the non-established method if it concludes that
 - a) the subject of verification of the non-established method are new procedures under Section 33 (1)
 - b) the verification of the non-established method is useful, and
 - c) the provider is competent to verify the non-established method.
- (2) The State Office for Nuclear Safety issues a binding opinion on the verification of the non-established method with medical irradiation based on a written request from the provider within 60 days from the date of its delivery. The request must include the data under Section 35 to the extent necessary to assess the non-established method in relation to medical irradiation and radiation protection.
- (3) The Ministry shall decide on the request under Section 35 within 90 days from the date of its receipt. In the case of verification of a non-established method with medical irradiation, the Ministry may decide to grant permission only on the basis of a binding opinion from the State Office for Nuclear Safety.
- (4) The decision to grant permission to verify the non-established method includes, in addition to the provisions of the Administrative Code
 - a) a definition of the non-established method,
 - b) a delimitation of the conditions under which the non-established method can be verified,
 - c) reporting deadlines for the different stages of the verification.

- (5) The Ministry may withdraw the permission to verify the non-established method if
- a) the Provider has violated the conditions set forth for verification of the non-established method by this Act or the permission to verify the non-established method based on the results of its own findings or the initiative of an ethics committee established by the Provider for verifying the non-established (hereinafter the "Ethics Committee");
 - b) the incentive to withdraw permission was given by the regional office that issued to the Provider an authorization for the provision of healthcare services (hereinafter referred to as the "Competent Administrative Authority"), which identified a breach of the conditions for the provision of healthcare services under this Act or other legal regulation in the framework of its inspection activity.
- (6) The Provider whose permission to verify the non-established method was withdrawn is required to terminate the verification without delay and to carry out such operations in order to avoid endangering the health or life of the patients.
- (7) The participant in the procedure for granting permission to verify the non-established method is a Provider who submitted an application pursuant to Section 35.

Section 37

Prior to commencing the verification of a non-established method, the Provider

- a) shall set up an Ethics Committee,
- b) shall take out liability insurance for health damage caused to patients in connection with the verification of the non-established method, with an insurance company which has been authorized to conduct insurance activity under the Insurance Act⁷; the extent of the insurance must correspond to the risks associated with the particular verified non-established method.

Section 38

- (1) The Ethics Committee is an independent committee whose task is
- a) to assess from an ethical point of view the verification of the non-established method,
 - b) to supervise the process of verifying the non-established method from the point of view of safety and the rights of the patients on whom the non-established method is verified.
- (2) The members of the Ethics Committee are health professionals and other persons, of which at least two thirds must not be in a labor-law or similar relationship with the Provider that has established it, a member of a supervisory body, a statutory body, a member of a statutory body or a partner of that Provider. The Ethics Committee must have at least 5 members. The Chairman and members of the Ethics Committee are appointed and removed by the Provider. Members of

the Ethics Committee may only be persons without personal interest in verifying the non-established method; a member of the Ethics Committee will make a declaration on this matter.

- (3) If during its activity the Ethics Committee discovers facts suggesting that the conditions under which non-established method can be verified are not being fulfilled, it shall immediately communicate these facts to the Provider and to the Ministry.

Section 39

- (1) The Provider verifying the non-established method is required
 - a) to submit to the Ministry within the deadlines set out in the permission to verify the non-established method reports on the individual stages of verification,
 - b) immediately suspend or stop the verification of the non-established method if there is reasonable doubt that the non-established method will not produce the expected result or that its verification could lead to a long-term or serious impairment of the health of the patient being verified; it is obliged to immediately notify the Ministry of this fact,
 - c) immediately notify the Ministry and the State Office for Nuclear Safety, if it has issued a binding assent, of the resulting adverse event; an adverse event is an unfavorable change in the patient's medical condition resulting from the verification of the non-established method,
 - d) to allow inspection during the verification of the non-established method by persons authorized by the Ministry, the State Office for Nuclear Safety, if it has issued a binding assent, or members of the ethics committee.
- (2) The Provider shall submit to the Ministry, within 30 days of the completion of the verification of the non-established method, a final report on the outcome of the verification, in which it shall also assess the non-established method in terms of the possibility for its use in the provision of healthcare services. Where a binding assent has been issued by the State Office for Nuclear Safety for the granting of permission for the verification of a non-established method, the Provider shall submit a report on the course of the medical irradiation and the radiation and relevant facts within 30 days after the end of the verification to the State Office for Nuclear Safety.

Section 40

- (1) On the basis of the final report on the outcome of the non-established method indicating the possibility of its use in the provision of healthcare services, the Ministry will assess whether the non-established method meets the conditions for introduction into clinical practice. When assessing the results of a non-established method, it shall take into account the benefits of this method for improving the health of patients.
- (2) The Ministry shall issue a decision by which the non-standard method

- a) shall be recognized as a standard method if, on the basis of the assessment referred to in paragraph 1, it concludes that the conditions for its introduction into clinical practice have been met and that the new standard method will contribute to improving the health condition of patients;
 - b) shall not be recognized as a standard method if, on the basis of the assessment of the non-standard method, it concludes that the conditions for its introduction into clinical practice have not been met.
- (3) The participant in the procedure under paragraph 2 is only the Provider who validated the non-standard method.
- (4) The Ministry shall publish in the Bulletin of the Ministry of Health and in a manner allowing for remote access
- a) the recognized standard method,
 - b) the unrecognized non-standard method, including the reasons that led to its non-recognition.

Chapter IV

Assessment care and medical opinions, occupational health services, occupational illness assessment (Section 41-69)

Part 1

Assessment care and medical opinions (Sections 41-52)

Section 41

Assessment care includes the assessment

- a) of medical fitness for education and during education (hereinafter referred to as "education") for the needs of schools and school facilities, or for physical education and sport or other activities under this Act or other legal regulations,
- b) of medical fitness at the needs and at the request of administrative authorities or other bodies in cases provided for by other legal regulations,
- c) medical fitness upon request by the patient or legal representative of the patient, or with their consent upon request by a legal person,

- d) medical fitness to work or to perform a service on the basis of a medical examination; the assessment of medical fitness for work or the performance of a service is mainly the assessment of employees' medical fitness according to Sections 53 to 58,
- e) health condition in relation to an occupational disease or threat of occupational disease (hereinafter referred to as "occupational disease"),
- f) health condition for the purpose of sickness insurance and for the needs of the Labor Office,
- g) the health condition of the patient for other purposes.

Section 42

- (1) A medical opinion on medical fitness or health condition (hereinafter referred to as a "medical opinion") is issued by the Provider at the request of the patient, who is the person under review, or another person entitled to do so, after assessing the medical fitness or, where appropriate, the health condition of the person being assessed by the assessing physician on the basis of an evaluation
 - a) of the results of a medical examination and other necessary professional examinations (hereinafter "medical examination"),
 - b) of an extract from the medical records kept on the assessed person by his/her registering provider in the field of general practical medicine or in the field of practical medicine for children and adolescents (hereinafter referred to as the "registering provider") if the person under assessment is registered with such a provider or, in the case of an assessed person whose health documentation is kept on the territory of another state, also on the basis of an extract from this documentation, accompanied by an officially certified translation into the Czech language; an officially certified translation need not be submitted to an extract from medical documentation kept in the Slovak language; the extract from medical documentation may be requested by the assessing physician through the person under assessment,
 - c) of the health demands for the performance of work, service, occupation, education, sport, physical education or other activity (hereinafter referred to as the "activity") for which the person is assessed, and the conditions under which the activity is performed, or the demands of the activity on the health of the person under assessment.
- (2) The medical opinion is issued by the registering provider of the assessed person, unless this Act or other legal regulation stipulates otherwise. The assessing physician is a physician with competence in the field of general practical medicine or a general practitioner for children and adolescents, unless this Act or other legal regulation stipulates otherwise.

Section 43

- (1) The medical opinion must be issued within 10 working days from the date of receipt or oral submission of the application pursuant to Section 42 (1), in the case of an opinion on the recognition of an occupational disease within 30 working days, unless otherwise stipulated in this Act or in any other legal regulation. The countdown to the deadline according to the first sentence does not start until the last necessary document for the assessment of medical fitness or health condition according to Section 42 paragraph 1 is received. A written request under the first sentence or a record of its oral submission form part of the medical documentation relating to the person under assessment. The record shall be signed by the assessing physician and the person who submitted the oral application.
- (2) For the purposes of assessing the continued validity of medical fitness, a medical examination of the person under assessment may be performed no earlier than 90 days prior the expiry date of the previous medical opinion, the validity of which shall not change unless the assessing physician detects a change in health condition leading to the issuing of a medical opinion with the conclusion pursuant to Section 44 (4) a). The deadline for the performance of the medical examination established by the public health authority or other legal regulation for the purpose of further assessment of the medical fitness of the person under assessment and the validity of the medical opinion shall, according to the first sentence, not be affected by the performed medical examination. This is without prejudice to the possibility of carrying out medical examinations due to changes in medical fitness or health condition, or suspicion regarding such changes.
- (3) It must be clear from the conclusion of a medical opinion whether the person under assessment is medically fit, medically unfit or conditionally medically fit for the purpose for which he/she is assessed, or whether he/she has become medically unfit in the long term, or whether his/her health condition satisfies the assumptions or requirements for which it was assessed. The medical opinion must include guidance on the possibility of submitting, under Section 46 (1), a review proposal to the provider who issued the opinion. The information shall further specify the deadline for the review proposal, from which date this deadline is counted down and whether or not the proposal has a suspensive effect pursuant to this Act or other legal regulation.
- (4) A copy of the medical opinion forms part of the medical documentation of the person under assessment. The assessment of medical fitness or health condition for the purposes of issuing a medical opinion shall be paid by the person requesting it, unless otherwise provided in this Act or other legal regulation. In the written medical opinion, corrections of obvious misstatements that do not affect its conclusion pursuant to paragraph 2 may be made. Corrections shall be made by the provider at the initiative of the person referred to in Section 44 (1) or on the basis of its own initiative. The person referred to in Section 44 (1) shall be notified of the correction of the opinion.
- (5) A medical opinion shall not be issued if the person under assessment refuses to undergo the medical check-up or examination which it entails; the assessing physician shall record this fact in the medical documentation kept on this person. If the assessment of the medical fitness of the assessed person has been requested by another authorized person, the provider shall notify it of the absence of an opinion, including the reason for not issuing it.

- (6) If a medical opinion has not been issued for the reason referred to in paragraph 5, or if the person under assessment has not undergone a medical examination for the purpose of further medical fitness assessment for another reason, the assessed person shall be regarded as being physically unfit for the activity for which he or she was to have been assessed, or as a person whose health condition does not meet the assumptions or requirements for which he/she was assessed.

Section 44

- (1) The provider who issued the medical opinion shall immediately ensure its demonstrable handover
- a) to the assessed person and
 - b) to a person who has legitimately requested the assessment of the medical fitness of the assessed person for the purpose of issuing an opinion, if this is not the person being assessed.
- (2) The demonstrable handover of the medical opinion referred to in paragraph 1 shall be deemed its acceptance
- a) by the person referred to in paragraph 1, confirmed by the signature of that person stating the date of the handover, and, in the case of the person referred to in paragraph 1 (b) or an authorized representative of that person, the number of his/her identity card or other identity document and the reason for issuing the opinion shall also be stated; the acknowledgment of receipt of the medical opinion is forms part of the medical documentation kept on the person under consideration,
 - b) on the basis of delivery by a postal service operator; the delivery must be accompanied by an advice of delivery, or
 - c) on the basis of an electronic delivery signed in the manner with which another legal regulation connects the effects of a handwritten signature in legal proceedings with the state in connection with the exercise of its powers²², in the mailbox of the person under assessment and the person who has requested the assessment of medical fitness.

The medical opinion shall also be deemed to have been demonstrably handed over if the person entitled to accept the opinion refuses to accept it or confirm its acceptance via signature; this fact shall be recorded by the assessing physician in the medical documentation kept on the person being assessed; the record shall be signed by the assessing physician and the another healthcare worker who is present during the handover of the opinion. In the event of a refusal to accept a medical opinion delivered through a postal service provider, the provisions of Section 9 (4) shall apply *mutatis mutandis*.

- (3) A person who is not a person referred to in paragraph 1 b) and who acquires rights and obligations through the application of the medical opinion, shall submit the opinion to the assessed person, unless this Act or other legal regulation stipulates otherwise.

(4) Legal effects of the medical opinion

- a) with the conclusion of medical disability, long-term loss of medical fitness of the person under assessment or conditional medical fitness apply to the person to whom it was submitted on the date of demonstrable handover,
- b) with the conclusion of medical fitness of the assessed person shall apply to the person to whom it was submitted on the date on which the validity of the previous assessment expires, but no earlier than the expiration of the period for filing a petition for review or the date of demonstrable delivery of the decision of confirmation of the opinion by the administrative authority which granted authorization for the provision of healthcare services,
- c) regarding health condition apply to the person to whom it was submitted on the date of expiry of deadline for submitting a petition for review, or on the date of the demonstrable delivery of the decision on the confirmation of the opinion by the administrative authority which granted the provider authorization for the provision of healthcare services.

(5) The medical opinion may be applied for the purposes for which it was issued within 90 days of its issuance, unless the opinion or another legal regulation provides for a shorter time limit. If the administrative authority that granted the provider authorization for the provision of healthcare services, confirms the contested medical opinion pursuant to Section 47 (2) a), such an opinion may be used by the authorized person for the purposes for which it was issued within 10 working days of the demonstrable delivery of the confirmed opinion.

(6) The medical opinion is invalid

- a) upon expiry of the period for which it was issued,
- b) on the date on which a medical examination was to be carried out in accordance with another legal regulation, decision of the public health authority or assessing physician or other authorized person for the purposes of reassessing the medical fitness of the person under assessment,
- c) on the date on which the legal effects of a medical opinion issued for the same purpose and under the same conditions as the previous opinion have occurred, unless otherwise provided in this Act or other legislation,
- d) upon termination of the employment or service relationship in the case of an opinion pursuant to Section 41 d); this shall not apply if, within a maximum of 3 months from the date of termination, a labor-law relationship with the same employment has been re-concluded with the same employer, if there has been no change or development in the health of the person under assessment since the moment of termination.

(7) If the medical opinion is invalid, the assessed person shall be regarded as medically unfit for the purpose for which he or she should have been assessed, or a person whose health condition does not meet the assumptions or requirements for which he/she was assessed.

Section 45

- (1) The assessing physician who establishes that the person under assessment is no longer able to perform an activity or to perform an activity conditionally, or that his health condition does not meet the assumptions or requirements for which he/she was assessed, shall notify the assessed person of this fact and forthwith also the person who through the application of the medical opinion acquires rights or obligations, if such a person is known to him/her. The person under assessment is considered to be medically unfit or conditionally fit, or a person whose health condition does not meet the assumptions or requirements for which he/she was assessed, until the legal effects of the new medical opinion become valid.
- (2) A physician who reasonably suspects that a change in the health of the patient has led to a change in his medical fitness or activity, or that the patient's health condition does not meet the assumptions or requirements for which he/she was assessed, is required to inform the patient and the provider responsible for issuing the medical opinion, if the provider is known to him/her or if the patient's address has been communicated to him/her. This information includes information about the patient's health condition that has led to the suspicion of a change in medical fitness or health condition.
- (3) In order to establish medical fitness or health status and issue a medical opinion on the basis of the information referred to in paragraph 2, the person under assessment shall be required to attend a medical examination at the request of the provider responsible for issuing the medical opinion or other authorized person within the prescribed time period.

Section 46

- (1) If the assessed person or a person who acquires rights or obligations through the application of a medical opinion believes that the medical opinion is incorrect, he/she may submit a petition for review to the provider who issued the opinion within 10 working days of the date of its demonstrable delivery. A person who acquires rights or obligations through the application of the medical opinion and to whom the opinion was handed over by the assessed person may submit a petition for review of the medical opinion within 10 working days of the date of its handover, to the provider referred to in the first sentence.
- (2) If the petition for review of the medical opinion is submitted after the expiry of the period referred to in paragraph 1, the provider shall defer the petition. The provider shall inform of this fact the person who submitted the petition for review of the medical opinion and the person who acquires rights or obligations through the application of the medical opinion, if known, and the assessed person, if he/she did not submit the petition. When demonstrating the reasons that objectively prevented the assessed person or other person from submitting a petition for review within the prescribed time limit, the provider shall pardon the missed deadline. Pardoning the missed deadline is without prejudice to the time limits set for the application of the medical opinion.

- (3) A petition for review of the medical opinion shall not have a suspensive effect if its conclusion implies that the person under assessment is not medically fit for the purpose for which he/she was assessed, conditionally medically fit or medically unfit in the long-term.
- (4) If the Provider fully complies with the review, the contested medical opinion shall be revoked without delay and, on the basis of the findings or a new medical fitness assessment, a new opinion shall be issued. The proof of cancellation of the opinion forms part of the patient's medical records.
- (5) If the Provider does not fully comply with the petition to review the medical opinion, it shall forward within 10 working days from the date of its receipt, in the case of a medical opinion on medical fitness, in other cases within 30 days, the file with a petition for review, including the documents necessary for the review of the medical opinion and its own opinion to the appropriate administrative authority.
- (6) The provider shall immediately notify in writing the person who acquires rights or obligations through application of the medical opinion, if known to him/her, and the person under assessment, if these are not the persons who submitted the petition, that the petition to review a medical opinion was submitted. It shall proceed in the same way if it fully complies with the petition to review the medical opinion, or if it submits the petition for review to the competent administrative authority. If the provider fully complies with the petition to review of the petition to review the opinion, it shall list in its statement according to the first sentence the facts that led to this decision.

Section 47

- (1) When reviewing a medical opinion, the competent administrative authority determines whether
 - a) the assessment of the medical fitness or health condition of the person being assessed was carried out and the medical opinion issued by an authorized provider,
 - b) medical examinations were carried out in accordance with the legislation or as advised by the assessing physician,
 - c) the health status of the person being assessed for the purposes of the medical assessment was fully ascertained and
 - d) the conclusion of a medical fitness assessment or health condition corresponds to the person's current state of health;the review of the medical opinion is based on the documents provided by the provider.
- (2) Within 30 working days from the date of receipt of the file with a petition for the review of the medical opinion, the competent administrative authority
 - a) shall reject this petition and confirm the contested medical opinion, or

- b) shall cancel the contested medical opinion and the matter will be returned to the provider for the issue of a new medical opinion, or
- c) the contested medical opinion shall be canceled.

The time limit referred to in the first sentence may be extended by an additional 15 working days in justified cases.

- (3) The competent administrative authority may, to the extent necessary for reviewing the medical opinion referred to in paragraph 1
 - a) require the provider to complete the documents submitted by him/her, and at the same time specify the period within which the provider is required to submit these documents; the provider is obliged to provide the necessary cooperation,
 - b) request expert advice from competent professionals under another legal regulation if it is necessary for a proper assessment of the procedure for issuing the medical opinion on the medical fitness or health condition of the person being assessed;

in such cases, the deadline referred to in paragraph 2 shall be interrupted.

- (4) The fourth part of the Administrative Code shall apply mutatis mutandis to the review of the opinion by the competent administrative authority, unless this Act provides otherwise.
- (5) A further petition for review of a medical opinion confirmed under paragraph 2 a) or canceled pursuant to paragraph 2 b) or c) by the competent administrative authority cannot be submitted. If the competent administrative authority confirms a medical opinion, a new assessment of the medical fitness or health status of the person being assessed may only be performed if it is apparent from the medical examination that the assessment of his/her medical fitness or health condition is likely to lead to a conclusion other than the one stated in the previous medical opinion.

Section 48

- (1) In the assessment of medical fitness and the issuing of a medical opinion pursuant to Articles 46 and 47, a similar procedure shall apply given that if the provider is
 - a) the Prison Service, a petition for the review of a medical opinion shall be submitted by the assessing physician to the Director of the Prison Service organizational unit where healthcare services are provided, who, according to Section 46, will review the medical opinion; if the Director of the Prison Service organizational unit does not fully comply with the request, he will forward it to the General Directorate of the Prison Service, which proceeds pursuant to Section 47,
 - b) the Security Information Service, a petition for the review of a medical opinion pursuant to Section 46 shall be reviewed by the assessing physician; if he/she does not fully comply with

the petition for review, he/she shall forward it to the Director of the Security Information Service, who will proceed pursuant to Section 47,

- c) the Office for Foreign Relations and Information, a petition for the review of a medical opinion pursuant to Section 46 shall be reviewed by the assessing physician; if he/she does not fully comply with the petition for review, he/she shall forward it to the Director of the Office for Foreign Relations and Information, who shall proceed pursuant to Section 47,
 - d) the Directorate General of Customs, a petition for review of a medical opinion pursuant to Section 46 shall be reviewed by the assessing physician; if he/she does not comply fully with the petition for review, he/she shall forward it to the General Director of the Directorate General of Customs, who shall proceed pursuant to Section 47,
 - e) the Ministry of the Interior, the assessing physician shall submit the proposal for the review of a medical opinion to the designated healthcare professional in a healthcare facility within the competence of the Ministry of the Interior or, where appropriate, the organizational unit of the state established by this Ministry, in which healthcare services are provided, and who shall, pursuant to Section 46, review the medical opinion; if the designated healthcare worker does not fully comply with the petition for review, he/she shall forward it to the Ministry of Interior, which proceeds pursuant to Section 47,
 - f) the Ministry of Defense, the assessing physician shall submit the petition for review of a medical opinion to the head healthcare worker of the healthcare services provider within the competence of the Ministry of Defense, who shall review the medical opinion pursuant to Section 46; if it fails to comply fully with the petition for review, he/she shall forward it to the Ministry of Defense, which proceeds pursuant to Section 47.
- (2) In the case of reviewing the medical opinion on the medical fitness of aviation personnel, the Civil Aviation Code shall be followed.

Common provisions for assessment care and medical opinions

Section 49

- (1) In the assessment of health condition for the purposes of sickness insurance, the provisions of § 41 to 48 shall apply mutatis mutandis, given that
- a) a document demonstrating the handover of a decision on temporary incapacity for work to the person under assessment and on the need for nursing and care to the person who requested the assessment of health condition is a record in the medical documentation signed by the assessed person, or the marking of the delivery date on the advice of delivery in the case of mailing through a postal license holder, ; in the case of electronic communication, a document of sending the decision on temporary incapacity for work of the assessed person is proof of sending through a data box or a record stored on the computer in electronic form in the formats stipulated by a legal regulation with the function of verify

the authenticity of the stored data and a time stamp obtained through a state recognized authority,

- b) the deadline for submitting a petition for review pursuant to Article 46 (1) shall be 3 working days; this petition has no suspensive effect,
 - c) the deadline for submitting the petition for review pursuant to Article 46 (5) is 5 working days,
 - d) the participant in the procedure for reviewing the decision is the provider that issued the decision and the person whose health condition is assessed; the petition for the review of a decision may be submitted by that person or by a person who acquire rights or obligations through the application of the decision.
- (2) If the patient is unable to sign due to his/her health condition or the patient refuses to sign the record according to paragraph 1 a), the healthcare worker shall record this fact in the medical documentation and simultaneously shall state the reasons for the absence of the patient's signature; the record shall be signed by the healthcare worker and a witness.
- (3) The legal regulation of health assessment for purposes of retirement, sickness, state social support, assistance in material need and benefits for persons with disabilities is not affected by the provisions of this Act.
- (4) The provisions on the obligation to maintain confidentiality under other legislation shall be applied in matters of expert judgment and medical opinion in such a way as not to shorten the procedural rights of the assessed person and persons who acquire rights and obligations through its application. This is without prejudice to other legislation which provides for the obligation to communicate certain facts or, where appropriate, for the obligation to keep certain facts confidential.

Section 50

During the deciding-making process of the sickness insurance authority on health status for the purposes of sickness insurance under another legal regulation⁸, the provisions of Sections 41 to 48 shall not apply.

Section 51

Assessment of medical fitness for education,

physical education and sport

- (1) Medical fitness for education is assessed and the medical opinion on medical fitness is issued by the registering provider. The assessing physician is a physician with competence in the field of general practical medicine or a general practitioner for children and adolescents, unless this Act or other legal regulation stipulates otherwise. In the case of applicants for education in schools and educational facilities established by the Ministry of Defense, medical fitness for education is

assessed and a medical opinion on medical fitness is issued by the healthcare service provider to whom the Ministry of Defense has granted authority to provide healthcare services in the healthcare facilities established by it; the assessing physician is a physician with competence in the field of general medical practice.

(2) If practical lessons or practical training takes place

- a) at the workplace of legal or natural persons, the medical opinion on the medical fitness of a person training for a profession prior to and his/her first assignment to the practical lessons or practical training and during that period is issued by the provider of the occupational health services of that person,
- b) in the workplace of a natural person who is self-employed, the medical opinion on the medical fitness of a person training for a profession prior to his/her first assignment to the practical lessons or practical training and during that period is issued by the registering provider of that person and, if the person does not have a registering provider, the provider of the school's occupational health services,
- c) only in a school or school facility, the medical opinion on the medical fitness of a person training for a profession prior to his/her first assignment to practical lessons or practical training and during that period is issued by the registering provider of that person and, if the person does not have a registering provider, the provider of the school's occupational health services,
- d) in the workplace of the persons referred to in points a) or b) and in a school or school facility, the medical opinion on the medical fitness of the person preparing for a profession prior to his/her first assignment to practical lessons or practical training and during that period, if the practical lessons or practical training are commenced

1. at school, the provider referred to in point c),

2. in the workplace of natural or legal persons, the provider referred to in points a) or b);

the assessing physician according to point a) is a physician with competence in the field of general practical medicine, the assessing physician according to points b) to d) is a physician with competence in the field of general practical medicine, practical medicine for children and adolescents, or occupational medicine.

(3) The assessment of the medical fitness of a person preparing for a profession before entering into practical training or practical preparation shall not be carried out

- a) if, in the context of practical training or practical preparation, an activity is carried out under conditions similar to the performance of the work included in the first category and if such work does not include an activity for the performance of which the conditions of medical fitness are prescribed by another legal provision²¹,

- b) if such training or education begins less than 12 calendar months from the date of the medical opinion referred to in paragraph 1 and if there has been no change in health condition during that period; the medical fitness assessment shall be carried out in this case no later than 12 calendar months from the date of inclusion of the person in practical training or practical preparation, or
 - c) if other legislation regulating the system of education in secondary and tertiary vocational education does not stipulate the conditions of medical fitness for education.
- (4) Medical fitness for
- a) physical education as part of educational programs and for sport for all⁹, and the conditions for the relief from lessons in the subject of physical education for one semester of the school year or a school year is assessed and the medical opinion is issued by the registering provider,
 - b) performance sports in organized sports competitions is assessed and the medical opinion is issued by the registering provider or provider in the field of physical education,
 - c) top-level sport, the sports representation of the nation and its preparation is assessed and the medical opinion is issued by the provider in the field of physical education medicine; for the purposes of this Act, top-level sport is understood to mean the field of sport which includes the national sports representation and the training of talented athletes for this representation, who are members of the sports centers⁹ or youth sports centers and similar facilities for the training of athletes,
 - d) education in schools focusing on sport and physical education, and during the course of teaching it is assessed and a medical opinion is issued by a provider in the field of physical education medicine.
- (5) In the case of a medical opinion issued by the registering provider, the assessing physician is a physician with competence in the field of practical medicine for children and adolescents or general practical medicine. In the case of a medical opinion issued by a provider in the field of physical education medicine, the assessing physician is a physician with competence in the field of physical education medicine.
- (6) A legal entity carrying out the activity of a school or school facility where education, including practical lessons or practical training, takes place, shall cover the assessment of the medical fitness of secondary school pupils or students of a higher vocational school, including medical examinations.

Section 52

The implementation legal regulation stipulates

- a) procedures for providing medical examinations, types, frequency and content of medical examinations necessary to determine the health of the person under assessment, and medical fitness assessment, including the scope of professional examinations,
- b) a list of diseases, conditions or defects that exclude or limit medical fitness to education or training, sport, physical education or other activities,
- c) the details of the medical opinion in relation to the activity under assessment.

Part 2

Occupational health services and medical fitness assessment of a person seeking employment (Sections 53-60)

Occupational health services

Section 53

- (1) Occupational health services are preventive health services, which include assessing the impact of work, the working environment and working conditions on health, performing preventive examinations and assessing health status for medical fitness assessment, counseling on occupational health and occupational safety, occupational diseases and work-related illnesses, first aid training and regular supervision of workplaces and work or service performance (hereinafter referred to as "work").
- (2) Occupational health services for employees and persons seeking employment are provided by the employer under the conditions laid down by this Act and by other legal regulations.

Section 54

- (1) The provider of occupational health services is
 - a) a provider in the field of general practical medicine, or
 - b) a provider in the field of occupational medicine.
- (2) For the performance of work at its workplaces, unless otherwise stated, the employer
 - a) in the case of work classified under the Public Health Protection Act as a first, second, second, third, or fourth risk category, or if part of the work is an activity for which the conditions are determined by other legal regulations, obliged to conclude a written agreement on the provision of a occupational health services with the provider referred to in paragraph 1,
 - b) in the case of works classified only in the first category under the Public Health Protection Act, and where such work does not constitute an activity for the performance of which

conditions are laid down by other legal regulations, may ensure the carrying out of occupational health inspections and the assessment of medical fitness for work on the basis of a written application with the provider referred to in paragraph 1 a), who is the registering provider of the employee or job seeker; other occupational health services pursuant to Section 53 (1) shall be provided by the employer via the provider referred to in paragraph 1, with whom the employer has concluded a written agreement,

- c) shall be obliged, in the case of a change in the classification of the work to a category higher than the first category under the Public Health Protection Act, or a change in the activity for the performance of which the conditions are laid down by other legal regulations, to conclude a new contract or supplement the existing written contract with the provider pursuant to paragraph 1 on those medical services which it has not yet requested no later than 3 months after the date of such change.
- (3) Medical fitness assessment and medical examinations for work that is or will be performed in trial operation under another legal regulation, are ensured by the employer via the provider pursuant to paragraph 2 a) or b) on the basis of the results of a risk assessment pursuant to another legal regulation or the measurement results, if it has been carried out for the purposes of consent to the trial operation.

Section 55

- (1) The employer is obliged:
- a) to enable authorized personnel of the occupational health services provider to enter each of their workplaces and to provide them with the information necessary to evaluate and prevent risks of potential life or health hazards at the workplace, including the measurement of working condition factors, to provide them with the technical documentation of the machinery and equipment, provide deciding information for health at work; in the case of workplaces which are subject to a special behavior for reasons of national or other legal protection, only the designated employees of the occupational health services provider can enter these establishments and are required to observe a special behavior,
 - b) to assigning employees to work according to the conclusions of medical opinions on their medical fitness,
 - c) when sending an employee to a medical examination pursuant to this Act or other legal regulations, to provide him/her with an application containing information on the type of work, the work regime and the working conditions to which the assessment of the employee is requested,
 - d) send the employee to an extraordinary medical examination, if requested so by the employee.

- (2) The employer has the right to send an employee to an extraordinary medical examination if he has doubts about the employee's medical fitness.

Section 56

The employee is obliged:

- a) to submit to the occupational health services of the provider with whom the employer has concluded a written contract or, where appropriate, to medical examinations and medical fitness assessment of a provider of occupational health services pursuant to Section 54 (2) b); he/she is also required to submit occupational health services indicated by the occupational health provider for health assessment; the providers of other health services are determined for the employee by the occupational health services provider; other healthcare services are included in the occupational health services,
- b) to submit to the occupational health services prescribed under another legal regulation,
- c) to communicate to the provider of the occupational health services the name and address of the registering provider and other providers who have accepted him/her into their care,
- d) to communicate to the provider of the occupational health services, at his/her own request or his/her own initiative, all known or suspected health-related work circumstances.

Section 57

- (1) The provider of occupational health services is obliged
- a) to inform employees about the possible influence of working condition factors on their health, with knowledge of the development of their health condition,
 - b) to inform the employer of the possible influence of working condition factors on the health status of its employees,
 - c) to perform regular supervision at the employer's workplaces and the work performed by the employees,
 - d) to cooperate with the employer, employees, occupational safety and health representative and qualified persons under the act governing the provision of additional health and safety conditions at work¹¹, trade unions and control bodies in the field of health and safety at work¹²,
 - e) to immediately notify the employer of the identification of serious or recurring facts that adversely affect safety and health at work,
 - f) to incite control bodies in the field of health and safety at work¹² to remedy compliance with obligations of health and safety at work¹³ if it finds that the employer does not proceed in

accordance with medical opinions or despite repeated warnings does not fulfill the obligations in the field of health and safety at work laid down by other legal regulations,

- g) to keep a record of occupational health services for the employer which does not apply to a particular employee, separately from the health records for specific employees; occupational health services documentation means records of the performance of supervision at the employer's workplace, including the results of analyzes, advice provided to the employer and other similar records of activities carried out within the framework of occupational health services,
 - h) to keep patient medical records separate from medical documentation kept on employees in the provision of occupational health services if he/she is the registering provider of the patient and at the same time a provider of occupational healthcare services.
- (2) An occupational health services provider is entitled to require the employer to provide measurements or expertise to analyze the working conditions, work environment and response of the employees' bodies', including the results of health risk categorization, if it suspects that there has been a change in working conditions that adversely affect or could affect the health of employees. The employer is required to ensure the measurement or expertise required by the provider under the first sentence. If he or she disagrees with the requirement to provide such measurements or expertise, he/she will seek the opinion of the competent public health authority under the Public Health Protection Act or the State Office for Nuclear Safety, if the work in question takes place in an ionizing radiation environment¹⁴. In the application, the employer must justify its refusal to provide measurements or expertise required by the provider of occupational health services.
- (3) The competent public health authority under the Public Health Protection Act or the State Office for Nuclear Safety examines the reasoning of the employer's request and will communicate its position in writing to the employer within 15 days of receipt of the request.

Section 58

The employer shall cover the occupational health services provided under this Act, except for the assessment of occupational diseases and the monitoring of the health condition in medical preventive examinations of occupational diseases and the development of health status during medical preventive examinations after the end of risk work, as provided for in the Act on Public Health Protection.

Section 58a

Provision of occupational health services by an employer on the basis of a labor- law or similar relationship

- (1) An employer who has been authorized to provide healthcare services under the Act on Health Services in the field according to Section 54 (1) a) or b) may provide occupational health services for work at its workplaces through
 - a) a physician with specialized competence in the field of occupational medicine or with a specialist qualification in the field of general practical medicine, and
 - b) other healthcare workers involved in the provision of occupational health services, with whom the employer has entered into a labor-law or similar relationship. The employer shall ensure the professional independence of the employees referred to in points a) and b).
- (2) In the provision of occupational health services pursuant to paragraph 1
 - a) an authorized employee pursuant to Section 55 (1) a) shall be the healthcare worker referred to in paragraph 1,
 - b) the employee is obliged to submit to the occupational health services of the physician referred to in paragraph 1 a); facts pursuant to Section 56 c) and d) are communicated to this physician,
 - c) According to Section 46, a medical opinion only may be reviewed by an employee who is a physician referred to in paragraph 1 a),
 - d) the employer is obliged to
 1. fulfill the obligations under Section 57 via the healthcare workers referred to in paragraph 1,
 2. ensure the fulfillment of other obligations and tasks which are provided by this Act or other legislation established for the healthcare services provider only via the healthcare workers referred to in paragraph 1.

Section 59

Occupational health services and medical fitness assessment of a person seeking employment (Sections 53-60)

- (1) In the case of a person seeking employment, the assessment of his / her medical fitness is carried out in a similar manner as for the assessment of the health fitness of employees in the framework of the occupational health services, given that
 - a) an initial medical examination shall be carried out with the provider of occupational health services with whom the employer has concluded a written contract, or with the registering

provider to whom the employer has sent a person seeking employment, unless otherwise provided by another legal regulation²⁰, and if the work referred to in Section 54 (2) b),

- b) the employer shall ensure the initial medical examination before entering into
 - 1. an employment relationship,
 - 2. an work agreement or agreement on work activity, if the person seeking employment is to be assigned to work which is high-risk under the Public Health Protection Act, or the work includes an activity for the performance of which the conditions of medical fitness are set by other legal regulations; the employer may also request an initial medical examination if it has doubts about the medical fitness of a person applying for work that is not high-risk, and is to be performed on the basis of a work agreement or agreement on work activity, or
 - 3. a relationship similar to an employment relationship.

A person seeking employment shall be deemed to be unfit to perform the work to which he is to be assigned unless he undergoes an initial medical examination under points 1, 2 or 3.

- (2) The initial medical examination is paid by the person seeking employment. The employer shall pay for the initial medical examination if it enters into an employment or similar relationship with the job seeker, unless otherwise provided by another legal regulation. The first and the second sentences do not apply if the person seeking employment or the employee agree otherwise with the employer or unless another legal regulation provides otherwise.

Section 60

The implementing legal regulation, unless otherwise provided by another legal regulation¹⁵, establishes

- a) procedures for providing medical examinations, types, frequency and content of medical examinations necessary to determine the health of the person under assessment, and medical fitness assessment, including the scope of professional examinations,
- b) the organization, content and scope of occupational health services and the content of documentation on occupational health services performed for the employer,
- c) occupational environment and disease risk factors, conditions and defects that, in the event of such factors, exclude or limit medical fitness to work or service,
- d) the details of the request for the performance of a medical examination and the assessment of medical fitness for work,
- e) the details of the medical opinion in relation to the activity under assessment.

Part 3

Occupational diseases (Sections 61-68)

Sub-section 1

Occupational disease assessment and recognition (Sections 61-65)

Section 61

- (1) The health condition of a person in connection with an occupational disease is determined and evaluated by providers of occupational health services.
- (2) Occupational diseases are assessed, recognized and the development of health status of persons with a recognized occupational disease are monitored by providers in the field of occupational medicine who have obtained permission from the Ministry for the recognition of occupational diseases, unless otherwise stated; for these purposes they may also carry out, if appropriate, a health examination to determine the health condition.

Section 62

- (1) The provider referred to in Section 61 (2) recognizes occupational diseases on the basis of
 - a) the determination of the health condition by the provider referred to in Section 61 (1), including the state of health prior to the disease and the results of the requested professional examinations and his/her opinion,
 - b) the results of further professional examinations, if justified, requested or performed by the provider referred to in Section 61 (2), and
 - c) verification of the conditions of occurrence of occupational diseases in accordance with paragraph 3.
- (2) For the purposes of assessment and recognition of the occupational disease, the provider referred to in Section 61 (1) shall submit to the provider referred to in Section 61 (2) a copy of medical records to the extent necessary to assess the disease. The procedure is similar if the disease of the assessed person continues not to satisfy the conditions for the duration of the occupational disease stipulated in the implementing legal regulation.
- (3) Verification of the conditions for the occurrence of occupational diseases¹⁶ is carried out
 - a) by the competent public health authorities under the Public Health Protection Act,
 - b) by the State Office for Nuclear Safety, in the case of a suspicion of the occurrence of an occupational disease in connection with work under conditions of ionizing radiation,

- c) by the provider of the occupational health services referred to in Section 61 (2), in the case of a suspicion of the occurrence of an occupational disease during the performance of work abroad, where the employee was sent by an employer with a registered office in the Czech Republic, on the basis of a communication by the assessed person and a detailed written statement of the sending employer on the conditions under which the work abroad was performed or other findings from the place of work performance; the results of the verification of the circumstances of the occurrence of the occupational disease are binding for the provider of assessing the occupational disease.
- (4) In the case of persons permanently living abroad, the assessment and recognition of occupational diseases is based on a medical report issued in the country of residence of the assessed person and certified by the competent authority of the country, unless published international treaties to which the Czech Republic is bound do not imply otherwise; the medical report must be accompanied by its officially certified translation into the Czech language; translation is not required in the case of a medical report in the Slovak language.
 - (5) The conclusion of a medical opinion must clearly state whether the disease of the person being assessed is recognized or not recognized as an occupational disease or whether the disease of the person under assessment no longer meets the conditions for recognition as an occupational disease prescribed by the implementing legal regulation. The provider referred to in Section 61 (2), who issued a medical opinion shall promptly ensure its demonstrable delivery to the persons referred to in Section 44 (1) and to other persons who obtain rights or obligations through the application of the medical opinion; these persons are defined by the implementing legal regulation.

Section 63

- (1) The attending physician is obliged to forward to the provider referred to in Section 61 (1) or (2) a person who, on the basis of a professional examination, is reasonably suspected to have developed an occupational disease, or to the provider referred to in Section 61 (2), if he/she suspects that the disease no longer meets the conditions for recognition as an occupational disease. The employer also has an obligation to forward employees to the provider referred to in Section 61 (1) or (2) if it reasonably suspects the development of an occupational disease, or to the provider referred to in Section 61 (2), if it suspects that the disease no longer fulfills conditions for recognition as an occupational disease.
- (2) If the provider referred to in Section 61 (2) discovers that he/she based the assessment of the occupational disease on incorrect, he/she shall, on his own initiative, reassess the health condition of the person being assessed; on the basis of a new assessment, a new medical opinion shall be issued. In such a case, the person under assessment shall be informed of this fact, as well as the persons for whom rights and obligations arise in connection with the application of a medical opinion, if such persons are known to the provider.
- (3) In case of a suspected occupational disease or suspicion that the disease no longer fulfills the conditions for recognition as an occupational disease, the assessed person is obliged to undergo

the professional examination indicated by the provider referred to in Section 61 (1) or (2), at a provider who designated by this provider. The provider referred to in Section 61 (1) or (2) shall disclose to the designated provider the facts which led to the suspicion under the first sentence. The designated provider is obliged to perform a professional examination on the date agreed with the person under assessment, but no later than 30 days from the date of communication by the provider of the occupational health services.

- (4) If the person under assessment refuses to undergo a professional examination, he/she is regarded as a person who does not suffer from an occupational disease. The provider must communicate this fact in a demonstrable manner to the person liable for damages to health, if such a person is known to him/her. A medical opinion is not issued.

Section 64

The employer is obliged to allow the authorized employees of the provider referred to in Section 61 (1) or (2) to enter a workplace where an employee or former employee works or has worked under the conditions under which the occupational disease under assessment has been developed, for the purpose of identifying other facts, conducting a clinical test, or taking a sample of the material or making an audiovisual recording needed to assess the occupational disease. The employer is also obliged to allow the former employee to enter the workplace in order to ensure the objectivity of the investigation and verification of the conditions of the occupational disease.

Section 65

The implementation legal regulation stipulates

- a) more detailed requirements for the assessment procedure and recognition of occupational disease,
- b) more detailed requirements for the assessment procedure of the occupational disease in cases where the disease continues to not satisfy the conditions for recognition as an occupational disease,
- c) the circle of persons to whom the providers referred to in Article 61 (2) submit a medical opinion on the occupational disease,
- d) the conditions under which the disease can no longer continue to be recognized as an occupational disease,
- e) the details of a medical opinion recognizing or not recognizing a disease as occupational.

Sub-section 2

Permission to recognize occupational diseases (Sections 66-68)

Section 66

- (1) The Ministry shall grant authorization for the recognition of occupational diseases to a provider in the field of occupational medicine on the basis of a request containing
 - a) the provider's identification data,
 - b) a copy of the authorization to provide healthcare services in the field of occupational medicine,
 - c) the scope and volume of healthcare services he/she is able to provide and their minimum staffing,
 - d) the duration of the provision of occupational healthcare services, which must be at least 5 years,
 - e) the technical and material equipment of medical facility,
 - f) the price for healthcare services not covered by public health insurance for which it intends to provide these healthcare services,
 - g) the number of individual examinations carried out and the number of persons assessed in relation to occupational diseases for the last 3 years prior to the submission of the application, if such an activity was carried out in the past.
- (2) The provider may submit an application following a call issued by the Ministry. The ministry's call includes
 - a) the place where the applications are to be submitted,
 - b) the deadline for the submission of applications,
 - c) the territories for which the healthcare services are to be provided,
 - d) the requirements for the scope and volume of requested healthcare services.
- (3) Upon examining the documents in the individual applicants' requests and facts contained therein, the Ministry excludes providers who have not complied with the conditions set out in the invitation, and in the case of others shall determine the order in relation to the territory in which the healthcare services are to be provided. Criteria for determining the ranking of applicants are the qualification prerequisite, the time and extent of practice and the range of services offered. Authorization to recognize occupational diseases may be granted to providers in the order designated by the first sentence. The authorization is granted for a period of 10 years.
- (4) The Ministry shall only grant authorization to a provider for which at least two doctors with a specialized competence in the field of occupational medicine assess and recognize occupational diseases, and if it has provided occupational health services for at least 5 years.

- (5) The authorization to recognize occupational diseases contains
 - a) the data referred to in paragraph 1 a),
 - b) the territories for which the healthcare services are to be provided,
 - c) the scope and volume of healthcare services provided.
- (6) The Ministry shall publish a list of providers authorized to recognize occupational diseases in a manner allowing for remote access.
- (7) If no provider applies for a given territory within the set deadline, or if the condition of at least two doctors with specialized competence in the field of occupational medicine performing the assessment of occupational diseases is not fulfilled, the Ministry shall ensure the recognition of occupational diseases by deciding of its own motion that occupational disease assessment shall be performed by one of the eligible providers. The Ministry shall only grant authorization to a provider for which at least two doctors with a specialized competence in the field of occupational medicine assess and recognize occupational diseases, and if it has provided occupational health services for at least 5 years.

Section 67

(15) The provider is obliged to notify the Ministry in writing of any changes in the data and conditions under which the authorization to recognize occupational diseases was granted, no later than 15 days from the date of their origin.

Section 68

- (1) The authorization to recognize occupational diseases expires
 - a) on the date of termination of authorization to provide healthcare services in the field of occupational medicine,
 - b) upon withdrawal of the authorization by the Ministry.
- (2) The authorization to recognize occupational diseases
 - a) shall be withdrawn by the Ministry if the provider so requests or does not provide the healthcare service for the territory specified in the authorization,
 - b) may be withdrawn by the Ministry if the provider ceases to fulfill any of the conditions under Section 66 (1) e) or (5) c).
- (3) In the case of a provider who has not been granted a new authorization for the recognition of occupational diseases after the end of the period for which he was authorized to recognize occupational diseases, the provisions of the Act on Health Services establishing the handling of

medical documentation similarly apply upon termination of the provider, with the Ministry taking over the medical documentation until it is transferred to the new provider responsible for the recognition of occupational diseases.

Part 4

Common provisions for occupational health assessment, occupational health services, and the assessment and recognition of occupational diseases for members of the security corps, armed forces and prisoners (Section 69)

Section 69

- (1) An employer is also understood to mean
 - a) the security corps that exercises the rights and obligations under another legal regulation towards a natural person who performs a service in the security corps (hereinafter referred to as "a member of the security corps"),
 - b) the armed forces of the Czech Republic exercising the rights and obligations under another legal regulation towards a member in a service relationship who performs the service,
 - c) prisons and institutions for the performance of security detention, in the case of persons in imprisonment, custody or security detention.
- (2) If the Prison Service is an employer, it provides occupational health services to employees and persons in custody, imprisonment or security detention assigned to work in its health facilities.
- (3) An employee is also understood to mean a member of the security corps or a member of the armed forces of the Czech Republic in a service relationship under another legal regulation. An employee is also understood to mean persons in custody, imprisonment or security detention, if they are assigned to work.
- (4) The place of work performance is also understood as the place stipulated by another legal regulation.
- (5) If another legal regulation provides otherwise for the assessment of the medical fitness of a member of the security corps or of the armed forces of the Czech Republic, or of a citizen who applies for recruitment to the security corps or an applicant for employment in the armed forces, the procedure is conducted pursuant to this other legal regulation.
- (6) The authorization to recognize occupational diseases by employees of the Ministry of Defense and the Army of the Czech Republic, pupils of military schools and employees of other budgetary and contributory organizations established by the Ministry of Defense is awarded to providers of

occupational medicine under the competence of the Ministry of Defense; the provisions of Sections 66 to 69 shall not apply.

Chapter V

Medical exposure and clinical audits (Sections 70-82)

Part 1

Medical exposure (Sections 70-73)

Section 70

- (1) Medical exposure means the exposure of natural persons to radiation under another legal regulation.
- (2) Clinical liability for medical exposure is the liability for individual medical exposures, in particular the justification for medical exposure, including the assessment of the goals of the medical exposure, its optimization, clinical assessment, practical cooperation with other healthcare workers, or obtaining information on the prior provision of healthcare services, providing information or records of medical exposure to other indicating physicians or administering professionals at their request, and the provision of information on the risk of ionizing radiation to exposed persons. The burden of clinical liability lies with the applying expert in the scope of his/her professional capacity.
- (3) An indicating physician means any attending physician or dentist who recommends, with his/her written justification, the patient for medical exposure to the applying expert. An indicating physician is required to assess any information about the patient's health condition that is relevant to the medical exposure known to him/her so as to avoid unnecessary exposure of the patient.
- (4) An applying expert is a physician, dentist or other healthcare worker authorized to perform medical exposure activities under another legal regulation and who is authorized to take clinical liability for individual medical exposures.
- (5) National radiological standards are procedures for the provision of healthcare services that include medical exposure and correspond to the current knowledge of science and clinical medicine (hereinafter referred to as "national radiological standards"). National radiological standards are issued by the Ministry; it publishes them, including their updates, in the Bulletin of the Ministry of Health and in a manner allowing for remote access.

Section 71

- (1) The provider who provides healthcare services which include medical exposure is required
 - a) to perform medical exposure only if its net benefit is demonstrate when considering the total possible diagnostic or therapeutic benefit, including a direct benefit to the health of the person or the benefit to society, as compared to the damage that the exposure may cause; the indicating physician and applying expert must be involved in the justification process; indication criteria for the justification of medical exposure are published and updated by the Ministry in the Bulletin of the Ministry of Health and in a manner allowing for remote access,
 - b) to develop local radiological standards and ensure compliance with them; when developing local radiological standards, it shall base them on national radiological standards, specific conditions at the workplace of the health facility and the extent of the provided health services,
 - c) to perform an internal clinical audit and, if it finds deficiencies on the basis of its results, take measures to eliminate them,
 - d) to ensure that an external clinical audit is carried out by authorized persons; if an external clinical audit reveals deficiencies, the provider shall take steps to eliminate them; if an external clinical audit reveals deficiencies not revealed by an internal clinical audit, the provider shall investigate the reasons for such non-disclosure and take appropriate action; the external clinical audit is not performed at the radiological workplaces of healthcare facilities equipped with dental X-rays or bone densitometers only,
 - e) to ensure observance of the rules of radiation protection during search examinations using ionizing radiation, verification of a non-standard method using medical exposure for which no binding opinion of the State Office for Nuclear Safety is issued pursuant to Section 36, and in patients who may or may have been exposed during pregnancy and breastfeeding.
- (2) The provider is obliged to ensure that
 - a) local radiological standards are available to all healthcare workers performing medical exposure,
 - b) in the provision of health services which include medical exposure, except for the provision of these services in radiological workplaces of medical establishments equipped only with dental x-rays or bone densitometers, the appropriate medical exposure activities are performed by a healthcare worker who is a radiological physicist with specialized competence, a radiological physicist, a radiological technician, a radiological assistant with a specialized competence or a radiological assistant, and that the healthcare worker is available at the provider's workplace; the method of ensuring the availability of this healthcare worker and the extent and manner of ensuring the activities performed by him/her during medical exposure shall be laid down by the implementing legal regulation,
 - c) during the provision of healthcare services which include medical exposure, radiation protection optimization has been carried out,

- d) follow-up theoretical and practical training of healthcare workers involved in medical exposure, taking into account new knowledge in the field of radiation protection,
 - e) measures have been taken to prevent the occurrence of an accident or the administration of an unplanned dose to the patient.
- (3) The registering provider of the patient is required to submit, at the request of the healthcare provider that provides healthcare services which include medical exposure, written information about the patient's health condition that is relevant to the medical exposure. This is without prejudice to the obligation under the Health Services Act to provide the information that is necessary to ensure the continuity of healthcare services.

Section 72

- (1) Medical exposure of patients in the context of verification of a non-standard medical exposure method for which no binding opinion of the State Office for Nuclear Safety has been issued pursuant to Section 36 may be performed only in particularly justified cases and using appropriate techniques so that only procedures conforming to national radiological standards are used.
- (2) The provisions on the verification of non-standard methods shall apply mutatis mutandis to the exposure of healthy persons or patients by voluntary participation in a biomedical research program, including exposure that does not have direct health benefits for the persons undergoing the exposure.
- (3) The implementation legal regulation stipulates
- a) the rules and procedures for the radiation protection of persons in the course of their medical examination or treatment, the content of activities of the indicating physician, applying expert and other workers involved in the medical exposure,
 - b) the rules and procedures for radiation protection in the framework of occupational health services and preventive healthcare,
 - c) the rules and procedures for the radiation protection of persons in voluntary participation of healthy persons or patients in the medical validation of non-standard methods associated with medical exposure,
 - d) the rules and procedures for the radiation protection of patients exposed during pregnancy and breastfeeding,
 - e) the rules and procedures for the evaluation of local radiological standards and their compliance with national radiological standards,
 - f) the minimum requirements for the staffing of an external clinical audit,

- g) the scope and method of optimization of radiation protection during medical exposure.

Section 73

National radiological standards include in particular

- a) the requirements for the professional, special professional and specialized competence of healthcare workers,
- b) the technical parameters of radiological devices on which medical exposure is performed, minimum equipment for their inspection and adjustment,
- c) the method of determining the patients doses; the requirements for the documents necessary for the estimation of the dose, the way they are evaluated and their recording,
- d) radiological procedures,
- e) the requirements for patient preparation for the examination and the process of the method itself.

Part 2

Clinical audits (Sections 74-82)

Section 74

- (1) The aim of the internal clinical audit is to verify and assess whether medical services involving medical exposure are conducted in accordance with local radiological standards and that the medical exposure quality system is adhered to.
- (2) An internal clinical audit is performed once a year, through persons who have a work-related or similar relationship with the provider and are professionally competent in the area in which the audit is to be performed.
- (3) The Provider keeps records of internal clinical audits in which he records the date of the audit, the findings made in relation to the objective set out in paragraph 1 and the name(s) and surname(s) of the persons who performed the internal clinical audit and their relationship to the provider.

Section 75

- (1) The objective of the external clinical audit is to verify and assess compliance with local radiological standards in the provision of healthcare services that include medical exposure. The results are compared with national radiological standards and, if desired, these activities are modified or, if

necessary, new standards are introduced. An external clinical audit is performed at least once every 5 years.

- (2) An external clinical audit may be carried out by a legal entity that has been authorized by the Ministry for this activity on the basis of a binding assent of the State Office for Nuclear Safety; the Ministry will require a binding opinion prior to issuing a decision to grant an authorization to conduct an external clinical audit. Authorization to conduct an external clinical audit cannot be transferred or passed on to another legal entity.
- (3) A legal entity is granted authorization from the Ministry to perform an external clinical audit upon its written request, if
 - a) it is not a provider or a partner of the legal entity that is the provider,
 - b) its statutory body or its member, or a member of its supervisory body, is not at the same time the statutory body or a member thereof, or a member of the provider's or the health insurance's supervisory body, nor is it the provider,
 - c) it has developed rules for the process of evaluating local radiological standards and their compliance with national radiological standards (hereinafter the "evaluation process rules") for individual areas of medical exposure; areas of medical exposure are understood to mean
 1. radiodiagnostics, including interventional radiology and cardiology,
 2. radiotherapy
 3. nuclear medicine and
 - d) is sufficiently staffed to conduct an external clinical audit to the extent required for authorization.

Section 76

- (1) An application for authorization to conduct an external clinical audit must also include, in addition to the details provided for by the Administrative Code,
 - a) the business name or name and address of the applicant's registered office,
 - b) the identification number, if assigned,
 - c) the name(s), surname(s), address of permanent residence in the Czech Republic or, in the case of a person without permanent residence in the territory of the Czech Republic, the address of residence outside the territory of the Czech Republic and, if applicable, the address of the place of residence declared in the territory of the Czech Republic and the date of birth of the persons who represent the provider's statutory body or its members, or who act on behalf of a legal entity registered in a commercial or similar register prior to its establishment,

- d) the date from which it intends to carry out the external clinical audit,
 - e) the area of medical exposure for which the authorization is to be granted.
- (2) The applicant shall attach to the application for authorization to conduct an external clinical audit
- a) a declaration that it is not the provider or a partner of the legal entity that is the provider,
 - b) a declaration by the statutory body or its members, or members of the supervisory body, that they are not simultaneously a statutory body or its members or members of the supervisory body of another provider and are not another provider,
 - c) proof that the legal entity was established or founded, unless entered in a commercial or similar register or if the registration has not yet been completed, or proof that the legal entity registered in the commercial or similar register; if the applicant is a legal entity established outside the Czech Republic, an excerpt from the commercial or similar register maintained in the state of residence and proof that the legal entity or organisational unit of a legal entity in the Czech Republic has been entered in the Commercial Register, if the entry has already been made; proof of entry in the commercial or similar register or the excerpt from such registers must not be older than 3 months,
 - d) a list of persons through whom the external clinical audit will be carried out, indicating the name(s) and surnames; for health professionals it shall also indicate their professional or specialised competence to pursue the medical profession and for other persons their education, indicating the study programme and the field in which it was acquired;
 - e) the rules of the evaluation procedure for individual areas of medical exposure.

Section 77

- (1) The decision on the authorization to conduct an external clinical audit in addition to the details provided for by the Administrative Code further contains
- a) the date from which the external clinical audit can be performed,
 - b) the medical exposure area for which the authorization is granted.
- (2) The Ministry shall send a written copy of the decision granting authorization to carry out the external clinical audit within 30 days of the effective date of the decision to the local tax authority administering income tax and to the local district social security administration and the State Office for Nuclear Safety.
- (3) The Ministry shall publish the list of persons authorized to carry out an external clinical audit, indicating the data referred to in paragraph 1 in a manner allowing for remote access.

Section 78

- (1) A legal entity that has been authorized to conduct an external clinical audit is required to disclose the evaluation process rules in a manner allowing for remote access.
- (2) A legal person authorized to carry out the external clinical audit shall be required to notify the Ministry in writing of any changes to the data contained in the decision to grant authorization, in the application for authorization and in the documents submitted together with that application, and to substantiate these changes by the relevant documents. Changes to data under the first sentence must be communicated within 15 days of the date on which they occurred.
- (3) Where a change concerns the information that is not listed in the decision to grant authorization to carry out the external clinical audit, and if the conditions for conducting the evaluation are still met, the Ministry shall make a record of this change in the file; in other cases, depending on the circumstances, the Ministry shall decide on whether to change the authorization or withdraw it.

Section 79

- (1) Authorization to conduct an external clinical audit expires
 - a) upon termination of the legal entity that has obtained this authorization,
 - b) by deletion of the legal person established outside the territory of the Czech Republic from the Commercial Register,
 - c) by the decision of the Ministry to withdraw the authorization.
- (2) The Ministry shall withdraw the authorization to conduct an external clinical audit if the legal person was granted this authorization,
 - a) has ceased to fulfill any of the conditions set out in Section 75 (3), or
 - b) it has requested the withdrawal of authorization.
- (3) The Ministry may withdraw the authorization to conduct an external clinical audit if the legal person has seriously or repeatedly failed to fulfill any of the obligations specified in Section 78 (1) or (2) or Section 81 (2), or has performed an external clinical audit through a person excluded from conducting external clinical audits pursuant to Section 81 (3).

Section 80

The Ministry shall send a written copy of the decision concerning a change or withdrawal of the authorization to carry-out an external clinical audit within 30 days from the effective date of the decision to the authorities referred to in Section 77 (2).

Section 81

- (1) A legal person that has been authorized to conduct an external clinical audit shall make an evaluation on the basis of a contract concluded between the provider and that person. The external clinical audit must be performed within 12 months from the date of conclusion of the contract.
- (2) A legal person conducting the external clinical audit is required in the performance of the evaluation
 - a) to proceed impartially,
 - b) to adhere to the evaluation process rules.
- (3) A person who is in a labour-law or similar relationship with the provider on whom the audit is being performed or performs for this provider the function of a professional representative, or is a partner of this provider, its statutory body or member of the statutory body, or a member of its inspection body, is excluded from performing an external clinical audit.

Section 82

- (1) The legal entity that performed the external clinical audit shall issue a report to the provider on the performance of an external clinical audit (hereinafter referred to as the "report").
- (2) The report shall contain
 - a) information on the legal entity that performed the external clinical audit, namely the business name or the name and address of the registered office and the identification number, if assigned,
 - b) information on the provider, which includes
 1. in the case of a natural person, the name(s), surname, address of permanent residence in the Czech Republic, or, in the case of a person without permanent residence in the territory of the Czech Republic, the address of residence outside the territory of the Czech Republic and, if applicable, the address of the place of residence declared in the territory of the Czech Republic, the identification number, if assigned, and the date of birth,
 2. in the case of a legal person, the business name or name, address of the registered office and identification number, if assigned,
 - c) the areas of medical exposure for which the external clinical audit was carried out and the place or places of the provision of healthcare services,
 - d) a description of the course and findings of the external clinical audit with respect to the objectives set out in Section 75 (1),

- e) the date of issue of the report.
- (3) The legal person that performed the external clinical audit shall issue to the provider upon request a confirmation of the performance of an external clinical audit. The confirmation shall contain the information referred to in paragraph 2 a) to c) and e).
- (4) A legal person conducting an external clinical audit keeps records of providers for which it has performed an external clinical audit.

Chapter VI

Protective treatment (Sections 83-89)

Section 83

- (1) Protective treatment is performed on the basis of a final decision of the court on the imposition of protective treatment (hereinafter referred to as the "court decision") as institutional protective treatment carried out in the form of inpatient care or as protective treatment carried out in the form of outpatient care.
- (2) The protective treatment imposed by the court can also be carried out during imprisonment in the medical facilities of the Prison Service, namely institutional protective treatment in the form of one-day care and protective treatment in the form of outpatient care. Conditions for the performance of protective treatment must not affect the conditions of imprisonment.
- (3) During the performance of protective treatment, only such limitations of human rights shall be applied as are prescribed by the law and to such an extent as is necessary to achieve the purpose of protective treatment, unless otherwise impossible to achieve.

Section 84

- (1) Providers are required, unless otherwise specified, to provide protective treatment outside of imprisonment if they are entitled to provide healthcare services in the field in which these activities belong.
- (2) The provider who performs protective treatment outside of imprisonment in the form of inpatient or outpatient care is, in addition to the rights stipulated by the Health Services Act, entitled to refuse to accept a patient for protective treatment if the acceptable workload would be exceeded by accepting this patient.
- (3) Protective treatment in addition to imprisonment is performed by the provider in the medical facilities of the Prison Service's medical facilities, if the conditions for providing healthcare

services are fulfilled under the Health Services Act. The medical facility of the Prison Service is part of the prison.

Section 85

(1) The provider ensuring protective treatment outside of imprisonment in the form of inpatient care may

a) exceptionally prohibit

1. a specific visit to a patient,
2. the use of phones by a patient, or
3. handing over correspondence to the patient,

if there are reasonable grounds for suspecting that they would seriously disrupt the individual treatment process; for this reason, it can also check patient's parcels; the reasons for the prohibition or control of parcels are recorded in the patient's medical records; the patient may not be forbidden to visit his legal representative or representative of the patient advisory organization, telephone use, and written communication when communicating with these representatives,

b) not allow the patient to leave the health care facility for a short time,

c) request the escort of the Police of the Czech Republic in the case of a patient whose participation in court is ensured by the provider and who could be dangerous to him/herself or the environment, or if there is a risk that he/she could escape.

(2) Limitation of correspondence or control of correspondence between the patient and the guardian established by the guardian, between the patient and his/her legal representative or representative of the patient advisory organization, between the patient and public authorities, the Ombudsman or the diplomatic mission or consular office of a foreign state, or between the patient and an international organization which, according to the international convention to which the Czech Republic is bound, is competent to handle claims concerning the protection of human rights, is inadmissible. This correspondence is sent to the addressee and is delivered to the patient without delay.

(3) Provider providing protective treatment outside the custodial sentence shall be obliged to ensure that the patient is provably acquainted with his / her rights and obligations related to the provision of health services in the health care facility during the protective treatment, with the expected time of healing and the possibility of changing the form of medical care care under Section 83 (1), in which the protective treatment is carried out, as well as with the individual treatment procedure, with the internal order of the care facility (hereinafter referred to as the "internal order"), unless submission of such information excludes his / her state of health. A record of informing the patient of his/her rights and duties forms part of the patient's medical

records. The record will be signed by the patient, a health worker and a witness who was present during the submission of information. The obligation to report to the patient on his/her health condition and the proposed health services under the Health Services Act is not affected by the first sentence. The patient's disagreement with the proposed individual medical treatment is also recorded in the medical records.

- (4) The provisions of paragraphs 1 to 3 shall also apply to protective treatment provided in addition to imprisonment, unless otherwise provided by other legislation.

Section 86

- (1) The provider ensuring protective treatment outside imprisonment in the form of inpatient care may, upon request, allow the patient to leave the healthcare facility for a short period of time, following an assessment of the patient's health condition; for this purpose it will issue him a pass.
- (2) A pass can be issued if the patient's health condition is stabilized and if it can be reasonably assumed that there will be no change during the short-term abandonment of the medical facility, which would lead to a behavioural disorder in connection to which protective treatment was ordered. Permission to leave the healthcare facility in the short term must not conflict with the purpose of the protective treatment and must not interfere with the individual treatment procedure.
- (3) The patient's request under paragraph 1 shall include the reasons for the short-term abandonment of the medical facility, the period for which permission is sought and the address of the place where the patient will reside. The pass includes the name(s), surname of the patient, his/her date of birth, the period for which it is issued, and the address of the place where the patient will reside. A written request or record of its oral submission and a copy of the pass form part of the medical records kept on the patient. If the provider refuses to issue a pass, the rejection is included in the medical records along with the reasons that led to it.
- (4) If a provider refuses to issue a pass, the patient may submit a new request within 7 days of the date of rejection of the original request.

Section 87

- (1) An provider ensuring protective treatment outside imprisonment may, in case of a serious violation of the patient's procedure of individual protective treatment, submit to the court which ordered the protective treatment a proposal to change the manner of its execution. If protective treatment is provided in addition to imprisonment, the the director of the Prison Service's organizational unit shall submit to the court a proposal for change of the method of executing protective treatment.
- (2) The provider ensuring protective treatment outside of imprisonment is obliged to notify the court that ordered the protective treatment that

- a) it cannot ensure that the patient receives protective treatment for the reason stated in Section 84 (2); this notification is a justification for refusing to accept the patient and a communication of the expected date of his/her possible acceptance,
 - b) a patient who has been ordered to undergo a protective treatment in the form of
 - 1. inpatient or outpatient care did not show up for protective treatment within the deadline set by the court,
 - 2. inpatient care has arbitrarily left the medical facility,
 - 3. outpatient care does not show up medical examinations within the given deadline,
 - c) the patient has been transferred to another workplace of the provider of the protective treatment or to the health facility of another provider on the basis of a sudden change in health condition which is not related to the protective treatment carried out in the form of inpatient care; if the patient has been appointed a guardian by the court, he/she shall also be notified by the provider of this fact.
- (3) The provider shall make the notification referred to in paragraph 2 within 24 hours of the occurrence of the fact referred to in paragraph 2.

Section 88

- (1) In addition to the obligations laid down by the Health Services Act, during protective treatment the patient is obliged to
- a) be subjected to an individual treatment procedure prescribed for protective treatment, including all healthcare provided as part of an individual treatment; this does not affect the right of the patient to choose from possible alternatives to treatment or his/her right to consent under the Health Services Act for individual medical procedures which are not directly related to the fulfillment of the purpose of the protective treatment,
 - b) be subjected, on the basis of a reasoned request by the attending physician, to a personal examination in order to ensure internal order and to prevent him or her from possessing anything that would interfere with the individual treatment procedure; the examination is performed by a person of the same sex,
 - c) allow employees designated by the provider to inspect his/her personal belongings,
 - d) in case of short-term leave of the medical facility, notify the address at which he/she will stay and comply with this place of residence; if the patient refuses to communicate this fact, he/she will not be issued a pass.

- (2) The provider shall make a record of the patient's medical documentation of the procedure referred to in paragraph 1 b) or c) and any follow-up measures.

Section 89

- (1) Costs related to the execution of protective treatment for persons not participating in public health insurance in the Czech Republic are paid by the state from the state budget of the Ministry.
- (2) A statement of account pursuant to paragraph 1 shall be sent by the provider to the Ministry no later than the fifteenth day of the following calendar month following the calendar quarter in which the health services were provided.
- (3) The state shall be entitled to recover from the patient the costs paid pursuant to paragraph 1 or a part thereof through the Ministry.

Chapter VII

Alcohol and drug sobering-up service (Sections 89a-89e)

Section 89a

Definition of the alcohol and drug sobering-up service

- (1) The anti-drug and anti-toxicological service is a health service provided to a person who, under the influence of alcohol or other addictive substance, does not control his or her behavior and is thus a direct threat to himself or another person, property or public order.
- (2) Sobering-up service is provided in the anti-alcohol and anti-drug sobering-up station (hereafter referred to as the "sobering-up station"). The sobering-up station is a medical facility.
- (3) The sobering-up service includes an examination of the person in order to ascertain whether his placement in the sobering-up station is not excluded for the reasons stated in Section 89b (2) a), and stay at the sobering-up station, including the necessary care to prevent health threats directly related to acute intoxication.
- (4) The sobering-up service is provided within its territory by the region in its independent scope.

Section 89b

Placement in the sobering-up station

- (1) A person who does not control his behavior under the influence of alcohol or other addictive substances and thus directly threatens himself or another person, property or public order and such a threat cannot be avoided through any other means has the obligation to undergo an

examination and stay at a sobering-up station, including the necessary care to prevent health threats directly related to acute intoxication, for as long as is necessary, but less than 24 hours.

- (2) It is not possible place a person in the sobering-up station who is
 - a) at risk of dying by failure of essential life functions, unconsciousness, has untreated wounds, massive bleeding, or a person showing signs of a disease immediately requiring care that cannot be provided at the sobering-up station; or
 - b) younger than 15.
- (3) A person may be placed in the sobering-up station only with the consent of the physician designated by the provider of the sobering-up service and subject to the conditions set out in paragraphs 1 and 2.
- (4) If a person to whom sobering-up service is provided immediately threatens himself/herself or another person or damages the property of the sobering-up service provider, and the provider of the sobering-up service cannot prevent this by its own means, this provider may request the necessary assistance from the Police of the Czech Republic, the Military Police, called for a preliminary examination or a professional medical examination according to the Act on Health Protection from the Harmful Effects of Drugs²² by a Military Police Officer, the Municipal Police or, in the case of persons in custody, security detention or imprisonment, the Prison Service.
- (5) The provider of the sobering-up service shall recommend professional care to the person placed in the sobering-up station.

Section 89c

Transfer to the sobering-up station

- (1) The transfer of an individual to the sobering-up station shall be ensured by the person who has invited the individual to undergo a preliminary examination or professional examination under the Act on Health Protection from the Harmful Effects of Drugs.
- (2) If a person who is transported to a sobering-up station during the provision of a medical rescue service or medical transport service is a direct threat to himself/herself or another person or damages the property of the provider of the medical rescue service or provider of the medical transport service healthcare provider and the provider of the medical rescue service or provider of the medical transport service cannot prevent this by their own means, it is possible for the provider to request the necessary cooperation of the Police of the Czech Republic and the Military Police, if the person invited to a preliminary examination or professional medical examination pursuant to the Act on Health Protection from the Harmful Effects of Drugs is a Military Police Officer, in custody, security detention or imprisoned by the Prison Service.

Section 89d

Reporting Duty

- (1) The examination and stay of the person in the sobering-up station shall be reported by the provider of the sobering-up service to the registering provider, if the provider is known.
- (2) The examination and stay of a minor in a sobering-up station shall also be reported by the provider of the sobering-up service
 - a) to his/her legal guardian, or other person responsible for his/her upbringing, and
 - b) to the authority for the social and legal protection of children.
- (3) In the case of a person with limited legal capacity, his/her examination and stay at the sobering-up station are also reported to the guardian.

Section 89e

Reimbursement of the cost of provided sobering-up services and transfer to the sobering-up station

- (1) If the presence of alcohol or other addictive substance is demonstrated, the costs of the sobering-up service shall be paid to the provider by the person who has received the sobering-up service; this person also pays the cost of transport to the sobering-up center to whoever incurred these costs. If the sobering-up service was provided to a minor who does not possess full legal capacity, the costs will be borne by his/her legal representative.
- (2) If the presence of alcohol or other addictive substance is not proven, the cost of the provided sobering-up service shall be paid to the provider by the Police of the Czech Republic, the Military Police, the Municipal Police, the Prison Service, the employer, the inspection body or the healthcare services provider, within whose competence a call to a preliminary examination or professional medical examination was made according to the Act on Health Protection from the Harmful Effects of Drugs. Whoever pays these costs also bears the cost of transport to the sobering-up station.
- (3) Where it is necessary for the provision of the sobering-up service to communicate with the person to whom the sobering-up service is provided via interpretation by a second person, and if the presence of alcohol or other addictive substance is proven, the costs of the interpreter shall be borne by the person to whom the sobering-up service was provided. Where the sobering-up service was provided to a minor who does not have full legal capacity, the costs of interpreting are covered by his/her legal representative. If the presence of alcohol or other addictive substance is not proven, the costs of interpretation shall be borne by the person who bears the costs referred to in paragraph 2.

Chapter VIII

Offenses (Sections 90-92a)

Act No. 183/2017 Coll., amends with effect from 1 July 2017 the title of chapter VII. However, it is clear from the context that this is the title of Chapter VIII.

Section 90

(1) The Provider commits an offense by:

- a) not ensuring that the patient is informed according to Section 15 (2) prior to the sterilization,
- b) establishing an expert committee whose composition or the relationship of whose member to the provider is contrary to Section 13 (3) or (4) in the case of sterilization,
- c) performing
 1. in violation of Section 14, sterilization for health reasons without the patient's written consent,
 2. castration according to Section 17 (2) without the written request of the patient pursuant to Section 17 (3) a) or the positive opinion of the expert committee pursuant to Section 17 (3) b) or without written request of the patient pursuant to Section 17 (4) a) or a positive opinion of the expert committee pursuant to Section 17 (4) b), or the consent of the court pursuant to Section 17 (4) c),
 3. the sex change of a transsexual patient under Section 21 (2) without the written request of the patient pursuant to Section 21 (3) a) or a positive opinion of the expert committee pursuant to Section 21 (3) b), or
 4. a psycho-surgical procedure pursuant to Section 24 (1) without the written consent of the patient pursuant to Section 24 (2) a) or the positive opinion of the expert committee pursuant to Section 24 (2) b), or without the written consent of the patient pursuant to Section 24 (3) a) or a positive opinion of the expert committee pursuant to Section 24 (3) b) or the consent of the court pursuant to Section 24 (3) c),
- d) performing
 1. sterilization for medical reasons without the written consent of the legal representative pursuant to Section 13 (2) a), a positive opinion of the expert committee pursuant to Section 13 (2) b) or the consent of the court pursuant to Section 13 (2) (c),
 2. the sex change of transsexual patients under Article 21 (2) without the written request of the legal representative pursuant to Section 21 (4) a), or a positive opinion of the expert committee pursuant to Article 21 (4) b), or the consent of the court pursuant to Section 21 (4) c), or

3. a psycho-surgical procedure without the written consent of the legal representative pursuant to Section 24 (4) a), or a positive opinion of the expert committee pursuant to Section 24 (4) b), or the consent of the court pursuant to Section 24 (4) c),
- e) performs sterilization, castration or a psycho-surgical procedure for other reasons or for on a person other than that provided for in Section 13 (1) or (2) in the case of sterilization, or Section 17 (2), (3) or (4) in the case of castration, or Section 21 (2), (3), (4) or (5) in the case of the sex change of a transsexual patient, or Section 24 (2), (3) or (4) in the case of a psycho-surgical procedure
- f) providing, selling or donating, in violation of Section 29 (2), the results of the genetic testing of a patient to third parties,
- g) allowing for intervention in the human genome for reasons other than those specified in Section 30 (1) or creating conditions for such intervention,
- h) in violation of Section 30 (2), allowing for the implementation of procedures designed to create a human being or create conditions for the implementation of such procedures or allow for the creation of a new human being,
- i) allowing procedures in conflict with Section 30 (3) or creating conditions for the implementation of such procedures,
- j) sampling blood in violation of Section 31 (2),
- k) issuing a medical opinion despite not being authorized to such issuing pursuant to Section 42 (2),
- l) not issuing an opinion within the time limit specified in Section 43 (1),
- m) not submitting a petition for the review of a medical opinion within the time limit set in Section 46 (5),
- n) in violation of Section 47 (3) a), failing to submit to the competent administrative authority on the basis of an invitation additional supporting documents, or failing to comply with the deadline,
- o) recognizing occupational disease, despite not not being authorized to recognize occupational diseases under Section 61 (2), or
- p) not sending, pursuant to Section 63 (1), a person who, on the basis of a professional examination, is reasonably suspected to have an occupational disease, or there is a suspicion that the disease no longer meets the conditions for recognition as an occupational disease, to the relevant provider.

(2) The provider that performs assisted reproduction methods commits an offense by

- a) disposing of human embryos in violation of Section 9,
 - b) in violation of Section 10 (1), not ensuring the maintenance of the anonymity of the anonymous donor and the infertile couple and the anonymity of the anonymous donor and the child born from assisted reproduction,
 - c) in violation of Section 10 (2), not preserve data on the health condition of the anonymous donor for a period of 30 years following the artificial insemination.
- (3) The provider validating a non-standard methods commits an offense by
- a) carrying out the validation of the non-standard method, even though the Ministry did not grant authorization to do so,
 - b) performing a validation of the non-standard method in violation of Section 33 (4) or (5),
 - c) not terminating validation of the non-standard method if authorization to validate has been revoked under Section 36 (5),
 - d) in violation of Section 37 a), failing to establish an ethics committee or establishing it in such a way that is in conflict with Section 38 (2),
 - e) in violation of Section 37 b), not concluding an insurance contract,
 - f) in violation of Section 39 (1) a), not reporting on the validation phase of the non-standard method,
 - g) in violation of Section 39 (1) (b), not interrupting or terminating the verification of the non-standard method,
 - h) failing to comply with the reporting obligation under Section 39 (1) c),
 - i) in violation of Section 39 (1) d), not allowing persons authorized by the Ministry, the State Institute for Nuclear Safety or members of the ethics committee to carry out inspections, or
 - j) in violation of Section 39 (2), not submitting a final report on the outcome of the validation of the non-standard method.
- (4) The provider of the occupational health services commits an offense by
- a) failing to comply with the reporting obligation under Section 57 (1) e), or
 - b) not providing pursuant to Section 57 (1) f) an impetus to inspection authorities in the field of health and safety at work.
- (5) The provider providing healthcare services that include medical exposure commits an offense by

- a) in violation of Section 71 (1) b), failing to ensure compliance with local radiological standards,
 - b) in violation of Section 71 (1) c), not performing an internal clinical audit pursuant to Section 74 (2)
 - c) in violation of Section 71 (1) d), not ensuring the performance of an external clinical audit in accordance with Section 75,
 - d) in violation of Section 71 (1) c) and d), not taking measures to remedy the identified deficiencies,
 - e) contrary to Section 71 (2) a), not ensuring that local radiological standards are available to all healthcare workers conducting medical exposure; or
 - f) contrary to Section 71 (2) c), not optimizing radiation protection.
- (6) The Provider providing protective treatment commits an offense by
- a) not ensuring protective treatment outside imprisonment, even if the conditions under Section 84 (1) are met and it is not the case of the procedure under Section 84 (2)
 - b) in violation of Section 85 (1) a), not record into medical documentation kept on the patient the reasons which led to the prohibition or control of the packages,
 - c) not providing information to the patient under Section 85 (3), or
 - d) failing to comply with the reporting obligation under Section 87 (2),
- (7) (4) A fine may be imposed for an offense of up to
- a) CZK 1 000 000 in the case of an offense under paragraph 1, h) or j),
 - b) CZK 500,000 in the case of an offense under paragraph 1 f) or o), paragraph 2 a) or paragraph 3 a), c), e) or g),
 - c) CZK 300,000 in the case of an offense under paragraph 1 a), c), d), e), k) or p), paragraph 3 b), d) or j), paragraph 5 a), b) or c) or paragraph 6 a),
 - d) CZK 200,000 in the case of an offense under paragraph 1 b), j), l), m) or n), paragraph 3 f), h) or i), paragraph 4 a) or b), paragraph 5 d) or paragraph 6 d), or
 - e) CZK 100,000 in the case of an offense under paragraph 2 b) or c), paragraph 5 e) or f), or paragraph 6 b) or c).

Section 91

- (1) A legal entity commits an offense by performing an external clinical audit despite not having been granted an authorization pursuant to Section 75 (2).
- (2) A legal entity authorized to conduct an external clinical audit shall commit an offense by:
 - a) in violation of Section 78 (1), not disclosing the rules of the evaluation process,
 - b) failing to comply with the reporting obligation under Section 78 (2),
 - c) in violation of Section 81 (2) b), failing to comply with the evaluation process rules when conducting an external clinical audit, or
 - d) in violation of Section 81 (3), conducting an external clinical audit via a person excluded from this evaluation.
- (3) (4) A fine may be imposed for an offense of up to
 - a) CZK 1 000 000 in the case of an offense under paragraph 1 b).
 - b) CZK 300 000 in the case of an offense under paragraph 2 a) or c),
 - c) CZK 200 000 in the case of an offense under paragraph 2 d).

Section 92

Infringements under this Act are handled by

- a) the competent administrative authority in the case of offenses pursuant to Article 90 (1), (2), (4) to (6),
- b) the Ministry, in the case of offenses under Section 90 (3) or Section 91 (1).
- c) the State Office for Nuclear Safety in the case of offenses under Section 90 (5).

Section 92a

- (1) A natural person commits an offense in violation of Section 89b (1) by failing to undergo an examination, stay or necessary care at a sobering-up station .
- (2) A fine of up to CZK 10,000 may be imposed for an offense under paragraph 1.
- (3) An offense under paragraph 1 is dealt with by the municipality in the delegated jurisdiction. An offense may also be dealt with on-the-spot an order of the Police of the Czech Republic or the municipal police.
- (4) The fine is collected by the authority that imposed it.

Chapter IX

Joint, transitional and final provisions (Sections 93-100)

Joint provisions

Section 93

The competence provided for by this Act to regional offices is the exercise of delegated jurisdiction.

Section 94

The activity of the members of expert committees established under this Act is another act of general interest¹⁸, for which they are entitled to compensation of salary or wage. Members of expert committees who are not in employment or a similar employment relationship but are gainful, are entitled to compensation for loss of earnings during the period of their participation in the activity of the committee, at the amount stated therein, but not higher than the average wage in the national economy declared and published by the Ministry Labor and Social Affairs in the Collection of Laws for Employment¹⁹. Members of expert committees are also entitled to the reimbursement of demonstrated travel expenses.

Enabling provisions

Section 95

- (1) The Ministry shall issue a decree implementing Section 52 a) and c) and Section 60.
- (2) The Ministry shall, in agreement with the Ministry of Education, Youth and Sports, issue a decree implementing Section 52 b).
- (3) The Ministry shall, in agreement with the Ministry of Labor and Social Affairs, issue a decree implementing Section 65.
- (4) The Ministry shall, in agreement with the State Office for Nuclear Safety, issue a decree to implementing Section 71 (2) b) and Section 72 (3).

Transitional provisions

Section 96

- (1) If a request for the performance of a healthcare procedure regulated by this Act was submitted before the date of entry into force of this Act, the assessment of this request shall be completed under the existing legislation. If the healthcare procedure regulated by this Act has already

commenced before the date of entry into force of this Act, it shall proceed from the date on which this Act enters into force in accordance with this Act, if it is for the benefit of the patient.

- (2) Providers validating a non-standard method under existing legislation are required to submit a request for consent to validate the non-standard method under this Act to the Ministry within 3 months of the effective date of this Act. The non-standard method can be validated by providers until the decision regarding the request is taken.
- (3) In compliance with the procedure under Section 9 (2), the provider may ensure the disposal of frozen human embryos created prior to the effective date of this Act, provided that a period of at least 10 years has elapsed since their creation.

Section 97

- (1) The Ministry shall publish the National Radiological Standards pursuant to Article 70 (5) within 6 months from the date of entry into force of this Act.
- (2) The provider who provides healthcare services which include medical exposure is required
 - a) to elaborate local radiological standards pursuant to Section 71 (1) b) within 1 year from the date of publication of the National Radiological Standards,
 - b) to perform the first internal clinical audit pursuant to Article 74 (2) within 2 years from the date of publication of the National Radiological Standards,
 - c) to conclude a contract pursuant to Section 81 (1) for the performance of an external clinical audit at all its establishments providing medical exposure within 1 year from the date of publication of the list pursuant to Article 77 (3).

Section 98

- (1) Occupational health services can be provided in accordance with existing legislation regulating the provision of preventive care for a maximum of 1 year from the date of entry into force of this Act. This is without prejudice to the obligation of the employer to compensate for preventive care in the scope provided for occupational health services pursuant to this Act from the date of entry into force of this Act.
- (2) If, prior to the effective date of this Act, a medical opinion has been requested and has not yet been issued, it shall be issued pursuant to this Act.
- (3) Medical opinions issued prior to the effective date of this Act shall be reviewed in accordance with existing legislation.

Section 99

- (1) The Ministry will issue the first invitation for applications for the issuing of an authorization to recognize occupational diseases within 3 months of the effective date of this Act.
- (2) The assessment of occupational diseases commenced prior to the issue of an authorization to recognize occupational diseases under this Act shall be completed according to the existing legislation.
- (3) Providers of Occupational Health Services listed in the annex to Regulation No. 342/1997 Coll., Laying down the procedure in recognition of occupational diseases and issue of the list of medical facilities which recognize such diseases, as amended until entry into force of this Act, shall recognize these diseases until the list is published in accordance with Section 66 (6). The Ministry shall notify them of the publication of the list at least 30 days prior to the publication of the list pursuant to Article 66 (6).
- (4) Providers referred to in paragraph 3 shall complete recognition of occupational diseases in cases commenced prior to the date of notification under paragraph 3.

Effectiveness

Section 100

This Act shall enter into force on the first day of the fourth calendar month following the day of its promulgation.

Němcová m. p.

Klaus m. p.

Nečas m. p.

Footnotes:

- 1 Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure and repealing Directive 84/466/EURATOM.
Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.
- 2 Act No. 296/2008 Coll., on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Use in Man and on Amendments to Related Acts (Act on Human Tissues and Cells), as amended.
- 3 Act No. 227/2006 Coll., on Research on Human Embryonic Stem Cells and Related Activities and on Amendment to Some Related Acts, as amended.
- 4 Section 179 of the Code of Civil Procedure.
- 5 CSN EN ISO 15189:2007 Medical laboratories – Particular requirements for quality and competence.
- 6 Act No. 22/1997 Coll., on Technical Requirements for Products and on Amendments to some Acts, as amended.

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- 7 Act No. 277/2009 Coll., on Insurance, as amended.
 - 8 Act No. 187/2006 Coll., on Sickness Insurance, as amended.
 - 9 Act No. 115/2001 Coll. on The Promotion of Sport, as amended.
 - 10 Act No. 258/2000 Coll., on Public Health Protection and on Amendments to Some Related Acts, as amended.
 - 11 Act No. 309/2006 Coll., stipulating further requirements for health and safety at work in labour-law relations and ensuring safety and health in activities or within services provided outside of labour-law relations (act on further requirements with regard to occupational safety and health), as amended.
 - 12 For example, Act No. 251/2005 Coll., on Labour Inspection, as amended, Act No. 258/2000 Coll., as amended, Act No. 18/1997 Coll., On Peaceful Utilisation of Nuclear Energy and Ionizing Radiation (Atomic Act) and amending and supplementing certain acts, as amended, Act No. 61/1988 Coll., on Mining Activities, Explosives and State Mining Administration, as amended.
 - 13 For example, Act No. 262/2006 Coll., Labour Code, as amended, Act No. 309/2006 Coll., as amended, Government Regulation No. 361/2007 Coll., laying down the conditions of health protection in the workplace, as amended by Government Regulation No. 68/2010 Coll.
 - 14 Act No. 18/1997 Coll., as amended.
 - 15 Act No. 361/2003 Coll., on the Service of Members of the Security Corps, as amended. Decree No. 393/2006 Coll., on medical fitness, as amended by Decree No. 407/2008 Coll. Act No. 221/1999 Coll., on professional soldiers, as amended. Act No. 585/2004 Coll., on conscription and its ensuring (the Conscription Act), as amended. Decree No. 103/2005 Coll. on medical fitness for military service.
 - 16 Government Regulation No. 290/1995 Coll., providing a list of occupational diseases, as amended by Government Regulation No. 114/2011 Coll.
 - 18 Section 200 et seq. of the Labour Code.
 - 19 Act No. 435/2004 Coll., on employment, as amended.
 - 20 For example, Section 247 of the Labour Code.
 - 21 For example, Act No. 49/1997 Coll., On Civil Aviation and Amending Act No. 455/1991 Coll., on Trades (Trade Licensing Act), as amended, as amended, Act No. 219/1999 Coll., on the Armed Forces of the Czech Republic, as amended, Act No. 221/1999 Coll., on Professional Soldiers, as amended, Act No. 361/2000 Coll. on Road Traffic and on Changing Certain Acts (Act on Road Traffic), as amended, Act No. 361/2003 Coll., on the Service Relationships of Members of the Security Corps, as amended, Act No. 585/2004 Coll., on Conscription and its Ensuring (Conscription Act), as amended, Government Regulation No. 211/2010 Coll., on the system of disciplines in basic and secondary education and vocational training, as amended, Decree No. 101/1995 Coll., issuing the rules for the health and professional competence in the operation of railways and railway transport, as amended, Decree No. 493/2002 Coll., on the assessment of medical fitness for the issue or validity of a firearms license and on the contents of the first-aid kit of the shooting range operator, as amended by Decree No. 254/2007 Coll., and Decree No. 352/2003 Coll., on the assessment of the medical fitness of employees of fire brigade units of enterprises and voluntary fire brigade units of municipalities or enterprises.
 - 22 21) Act No. 65/2017 Coll., on Health Protection from the Harmful Effects of Drugs.