PATIENT RIGHTS IN THE EU
SLOVAKIA

EUROPEAN ETHICAL - LEGAL PAPERS N° 14
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Within the Centre for Biomedical Ethics and Law of the Catholic University of Leuven - one of the leading bioethical and legal research centres in Europe - we are involved as coordinator, partner or participant in different European research projects. Biomedical ethics and law are rapidly evolving disciplines. Although there exists already a great number of specialized peer reviewed journals and series of books in both disciplines we felt a growing need for a medium through which the results of our research can directly be presented to the research community and the interested community at large. To meet this need we decided to start the *European Ethical-Legal Papers*. Such papers will also contribute to the transparency we owe to society that finances our research efforts. We also hope that it will contribute to the discussion and the exchange of information and ideas among researchers in Europe and elsewhere.

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EuroGentest is a five-year EU funded program that aims to develop the necessary infrastructure, tools, resources, guidelines and procedures that will lead to the establishment of harmonized, qualitative genetic testing services in Europe. Within EuroGentest we are dealing with the ethical and legal issues of genetic testing. Harmonization of the technical aspects of genetic services in Europe requires a legal and ethical framework that respects cultural, religious, philosophical and other domestic characteristics of a given country and its population(s), but at the same time conforms to basic and universally accepted human rights. To continuously supervise the legal and ethical developments regarding the promotion and protection of the rights of patients and users of health services and to make the results of our research publicly available, is a permanent challenge. This publication in the European Ethical-Legal Papers aims to contribute to it.

Opened for signature more than 10 years ago (in Oviedo, Spain, on 4 April 1997), the European Convention on Human Rights and Biomedicine is now becoming increasingly important as a standard to evaluate the efforts and the progress made by the Member States of the European Union to promote and protect the rights of patients and users of health services. In this fourteenth issue we present the results of this evaluation for Slovakia, one of the EU Member States that have ratified the Convention.

The content of this publication is as follows.
In an introductory chapter we briefly describe Slovakia with respect to some of its main features related to its political and legal background and its health care system.
This is followed by an encompassing overview of the rights of patients in Slovakia. In a first paragraph the legal status of the Biomedicine Convention is situated against the background of Slovak constitutional law. Then we turn to a description of the national legislation on patient rights. Many different enumerations of patient rights exist. Since we are particularly interested in the way the
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Biomedicine Convention has been received by the Member States of the European Union, we follow the structure of the Convention. The right to informed consent (articles 5, 6, 8 and 9 of the Convention) comes first, followed by different aspects of the right to private life and the right to information (article 10 of the Convention) such as: patient rights regarding the medical file, the right to medical secrecy/confidentiality and the right to privacy and protection of private life. This part of the analysis ends with the right to complain in case of unlawful infringement of a patient right (article 23 of the Convention) and the right to compensation for undue damage (article 24 of the Convention). In the next chapter we look at the rights of patients as users of genetic services: are the rights of patients complemented by more specific rights for users of genetic services? (articles 11 and 12 of the Convention). With some concluding remarks we finish this paper N° 14 of the Ethical-Legal Papers.

Without the help of Peter Kováč (Medical Faculty, Comenius University and Faculty of Law, Trnava University) we could not have accomplished this work. He provided us with valuable information on the status of patient rights in Slovakia and answered our questions accurately and patiently. In the footnotes we refer to the information provided by him as "personal communication of". The possible mistakes and wrong interpretations are our responsibility. We are also aware of the limitations of this endeavor not the least because of differences in languages. Nevertheless we hope that this publication will stimulate the discussion on the promotion and protection of patient rights in Slovakia. Therefore we welcome all reactions on www.cbmer.be.

Leuven, January 2008

*The research for this publication was supported by the Eurogentest Network of Excellence of the EU, FP6 – 512148 and its coordinator Prof. Dr. J.J. CASSIMAN*
II. BRIEF DESCRIPTION OF SLOVAKIA

§ 1. Political and legal system

After the peaceful separation of Czechoslovakia, the Czech Republic and Slovakia went their separate ways in 1993. Slovakia is a unitary state and a parliamentary democratic republic. The head of state of the Slovak Republic is the President. He is elected by direct popular vote for a term of five years. His position is relatively weak.¹ The President represents Slovakia in the external relations, he negotiates and ratifies international treaties and he signs acts adopted by the Slovak Parliament. He may refuse to sign an act and return it to the Parliament with comments for repeated consideration. However, if the act is passed through the Parliament a second time, it is adopted automatically. Furthermore, the President appoints and recalls the Prime Minister, members of the Government and heads of diplomatic missions.

The Government headed by the Prime Minister is the supreme executive body in Slovakia. Most of the executive power lies with the Prime Minister. He is usually the leader of the winning party, but needs to form a majority coalition in the Parliament. The remainder of the cabinet consists of the deputy Prime Minister(s) and the other ministers. They are appointed by the President on the recommendation of the Prime Minister. The Government is responsible to the National Council of the Slovak Republic for the exercise of governmental powers. The National Council has the power to take a vote of no confidence at any time.

The legislative power is vested in the unicameral National Council of the Slovak Republic (or Narodna Rada Slovenskej Republiky). This highest legislative body consists of 150 members, all elected for a four-year term on the basis of proportional representation. To be able

to enter the Parliament, a political party has to obtain at least five percent of the votes.  

The judicial system in Slovakia consists of District and Regional courts and the Supreme Court of the Slovak Republic, which is seated in Bratislava. Within the courts there are specialized judges or senates for penal, civil, commercial and administrative cases. The President of Slovakia appoints and recalls judges on the proposal of the Judiciary Council of the Slovak Republic. The term of the judges is not limited.

The Constitutional Court is the supreme judicial body protecting the Slovak Constitution. The Court has the power to rule on constitutional issues. The thirteen members of the Constitutional Court are appointed by the President from a list of candidates nominated by the National Council for a twelve-year term.

Slovakia is subdivided administratively into 8 regions, each of which is seated in the largest Slovak towns. They are further divided into 79 districts. The regions have enjoyed a certain degree of autonomy since 2002. Their self-governing bodies are referred to as Self-Governing Regions or Upper-Tier Territorial Units. Municipalities act as self-governing bodies on the local level.

§ 2. Health care system

Like in many other formerly communist countries of central and eastern Europe, the collapse of the communist system initiated in Slovakia important health care reforms. The main objective of those reforms was to improve the health status of the population. This should be ensured by radical changes in the structure, management and financing of health care.  


Reform of the health care system in Slovakia has focused mainly on the transition from a state owned, centrally planned, fee-free national system to a more decentralized system.\(^4\) The large-scale privatization of primary care physicians and pharmacies began in the mid-1990s. A second wave of privatization started in 2001 when the possibility of going private was extended to other health care facilities such as local health centers, polyclinics, rehabilitation institutions etc.\(^5\)

The Ministry of Health is the main central executive body responsible for health care and health protection. The Act No. 576/2004 Coll. of 22 September 2004 on healthcare, healthcare-related services and on the amendment and supplementing of certain laws determines the responsibilities of the Ministry of Health, such as the proposal of the principal directions and priorities of state health policy, the preparation and submission of the appropriate draft legislation to the Government and the supervision of the health care provision (section 45 of the Act on Health Care).

Besides the Ministry of Health, several other Slovak bodies and institutions take also part in the regulation of the health care system, such as the State Institute for Drug Control, the Health Care Surveillance Authority, the Public Health Authority, local health administrations and the professional associations.

The Slovak Constitution ensures universal coverage and access to free of charge health services based on mandatory health insurance, built on the principles of solidarity and plurality. In addition to this, the Constitution provides everybody with the right to protection of their health (article 40). In 1993 a social health insurance system was introduced. Since then the entire population of Slovakia is covered by mandatory health insurance.


Because of the growing debt in the sector due to the fact that the whole health care system was under-funded and poorly managed, a profound reform of the health care system was needed. The first step was taken in 2003 when the marginal co-payments of the patient were introduced. This additional source of funding by the patients contributed to the stabilization of the funding of the health care. After the adoption of important new legislation in 2004, the funding of the health care providers by the health insurance companies has changed. Primary outpatient care is now funded by capitation combined with fee-for-service payment. Secondary outpatient care is funded by capped fee-for-service payments. Hospitals on the other hand, receive per case payments, long-facilities are funded by payments based on bed days and the newly introduced one-day surgery care is funded per case.

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III. GENERAL PATIENT RIGHTS

§ 1. Legal status of the Convention on Human Rights and Biomedicine


According to article 7 (5) of the Slovak Constitution international treaties on human rights and fundamental freedoms, international treaties for whose exercise a law is not necessary and international treaties which directly confer rights or impose duties on natural persons or legal persons and which were ratified and promulgated in the way laid down by a law, shall have precedence over any domestic law. Consequently, the Convention has a superior force to any national legislation and is directly applicable in Slovakia.

However, it soon became clear that ratification alone was insufficient to strengthen the protection of the rights of patients in Slovakia.⁷ In 2004 a new health care system has been introduced by adopting new legislation. The reform package of six Acts became effective as of 1 November 2004, among which Act No. 576/2004 Coll. on health care and health care-related services (see §2).

Slovakia has not made any restrictions on the exercise of the rights contained in the Convention on the basis of article 26 of the Convention.

§ 2. National legislation on patient rights

The Slovak Constitution, the health care reform package of six Acts from 2004 and subsequent legislation create a comprehensive legal framework of patient rights in Slovakia. However, patient rights as such are laid down in the Act No. 576/2004 Coll. on health care and health care-related services and on the amendment and supplementing of certain laws as amended.

The Act on Health Care was established in 2004 following several initiatives taken in order to strengthen the protection of the rights of patients, since the patients were generally not aware of their rights. Although its predecessor, the Act on Health Care of 1994, introduced several changes which also affected the patient rights, the main problem remained the same.

A draft proposal of a charter was presented as part of the “Patients’ Rights in the Slovak Republic”-project in the framework of the Phare Programme financed by the European Commission. The final report of this project covering the period of November 1999 until October 2000 made several analyses. This resulted in observations such as the fact that the current legal regulations in the rights of patients were too general, too stringent and not patient friendly, the fact that several patient rights were literally scattered in different legal norms and the fact that some patient rights were neglected and some should be more detailed or better specified.

In April 2001 the Charter of Patients’ Rights was adopted by the Slovak Government. The preamble of the Charter states: “This charter was worked out in accordance with documents of the UNO, World Health Organization, Council of Europe and European Union. It takes into account the experience of the European countries, in particular the Netherlands, Germany, Sweden, Austria and the United Kingdom”.

Although the Charter, and its well defined summary of all patient rights, was the first step in improving the situation, applying these rights in everyday practice was necessary. The Dutch Government was approached for international cooperation and expertise. As a result of this cooperation, the project “Promotion of Patients’ Rights in Slovakia” was implemented and financed by the government of the Netherlands in 2002 and 2003. Two national conferences contributed to the development of the national policy on patient rights in Slovakia. They enabled an exchange of ideas, experience and good examples of patient rights promotion between both Dutch and Slovak participants. As a result of those conferences the “National Program of Patients’ Rights” was adopted and the “Patients’ Rights Unit” was established at the Slovak Ministry of Health as an administrative support.  

However, legislation on patient rights in Slovakia remained insufficient. In order to supplement and to extent the patient rights, drafting a separate law was suggested by the Center for Economic Development. In 2004 a new health care system has been introduced by adopting new legislation. The reform package of six Acts became effective as of 1 November 2004, among which Act No. 576/2004 Coll. on health care and health care-related services.

§ 3. Right to informed consent

Article 5 of the Biomedicine Convention:

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

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A. Right to informed consent as a basic requirement

The right to informed consent is included as one of the basic patient rights in section 4 of the Act on Health Care concerning the initial provisions of health care and health care-related services. The fourth paragraph of section 4 stipulates that an informed consent is required for health care provision, unless the Act on Health Care provides otherwise. This general provision is elaborated in section 6 which is entitled “Instruction and Informed Consent”. According to section 6 (4) an informed consent is a proven consent with medical interventions preceded by information related to the health care delivery or a proven consent preceded by a refusal of that information, unless the latter is stipulated otherwise in the Act on Health Care. According to section 6 (5) the informed consent shall be given by the person receiving the health care or by a legal representative if the patient is incapable to give an informed approval.

B. Contents of information preceding informed consent

The first paragraph of section 6 of the Act on Health Care stipulates that the attending medical professional is obligated to inform the patient of the purpose, nature, impact and risk of the medical interventions, of possible alternatives for the proposed procedures and of the risks of refusing health care. Section 11 (8) c) of the Act contains a similar provision. Section 6 (1) also specifies to whom the information should be given. This is in the first place the person receiving the health care or another determined person. If the person who receives health care services is a child, a person who is deprived of the capacity to execute legal acts or a person who is incapable to give an informed consent in an appropriate way, the information should in the second place be provided to a legal representative, tutor, foster or other person having an under-aged child in his or her personal care. The Act on Health Care does not contain a specific provision with regard to the standard that has to be taken into account regarding the risks that have to be revealed. According to KOVÁČ it is advisable to inform the patient both of the normal and the exceptional risks.12

12 Personal Communication of P. KOVÁČ.
According to section 6 (2) the information should be given to the patient in a comprehensible, understandable manner without any restraint, with sufficient time and with the possibility to opt freely for informed consent. The information should also be given in a way that is adjusted to the intellect, the will and the health condition of the patient. Although the Act on Health Care does not provide it as such, the information can be given to the patient orally.13

Whoever is entitled to information in accordance with section 6 (1), is also entitled to refuse it. A written record of this refusal of information shall be made in the medical file (section 6 (3)). The refusal of information has no consequences regarding the validity of consent since section 6 (4) explicitly defines an informed consent as a proven consent with a medical intervention preceded by information or preceded by a refusal of that information.

The method of information, the content of the provided information, the refusal of information, the informed consent and its eventual withdrawal has to be recorded in the medical records (section 6 (9)).

While the party who has filed the suit generally carries the burden of proof in a civil procedure, the physician has the obligation to proof in the case of health care services that he informed the patient and that the patient gave his consent to the provision of health care.14

C. Form of informed consent

The Act on Health Care does not specify the form in which the informed consent should be given. Although the Act does not generally require a written form, a written informed consent is necessary in specific situations such as the participation in biomedical research (section 27 (1)), removal of organs, tissue or cells form the body of a living donor (section 36 (2)), transfer of organs, tissue and cells to the recipient (section 38 (1)) and sterilization (section 40 (2)).

13 Personal Communication of P. KOVÁČ.
14 Personal Communication of P. KOVÁČ.
D. Exceptions to the requirement of informed consent

**Article 8 Biomedicine Convention**

*When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.*

An informed consent shall not be required in certain specific situations which are listed limitatively by the Act on Health Care. According to section 6 (8) of the Act health care provision without the patient’s informed consent is allowed in case of emergency care if it is impossible to gain the informed consent on time and if the consent can be presumed. It is also allowed in case of a protective treatment ordered by a court pursuant to separate legislation. Furthermore, an informed consent shall not be required in case of inpatient care if there is a risk of a serious deterioration of the health condition of the patient, if the patient spreads a contagious disease which seriously endangers his surrounding or if the patient endangers himself or his surrounding due to a mental illness or due to a disease with symptoms of a mental defect.

Hospitalization without the patient’s consent is subjected to a reporting duty. A health care provider is obligated to notify the competent court within 24 hours of the hospitalization of persons spreading an infectious disease or being mentally ill. In accordance with the special procedure as defined in section 191 of the Slovak Code of Civil Procedure the court has to rule whether the admission without informed consent has been permissible within 5 days from the day of admission. The patient should be released without any delay when the court judges that the hospitalization was not permissible without informed consent. If the hospitalization without consent however was permissible, the court has to determine within three months the length of the patient’s stay in the health care facility. Although the maximum term is one year, this can repeatedly be

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extended with another term of one year by a new court ruling. If the condition of the patient improves before the expiration of the term set out by the court, the patient should be released immediately.

E. Refusal and withdrawal of consent

The Act on Health Care acknowledges the right of patients to refuse a medical treatment. According to section 11 (8) d) of the Act each person is entitled to refuse health care, unless the provision of health care is even allowed without the patient’s informed consent in accordance with section 6 (8). The Act does not explicitly specify the form of refusal. However, the refusal of informed consent shall be recorded in the medical file of the patient (section 6 (9)). The attending medical professional is in accordance with section 6 (1) obligated to inform the patient of the risks of the refusal of health care.

As regards to the withdrawal of consent, section 6 (7) stipulates that whoever is entitled to give an informed consent in accordance with the first subsection shall also be entitled to withdraw it freely at anytime. The Act on Health Care also stipulates in section 12 (7) that the patient can withdraw the agreement to provide health care even without giving reasons (section 12 (7)). This refusal has to be submitted in writing.

F. Previously expressed wishes

<table>
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<th>Article 9 Biomedicine Convention</th>
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*The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.*

Previously expressed wishes relating to a medical intervention are not regulated in Slovak health law.

As the European Convention on Human Rights and Biomedicine is directly applicable in Slovakia, the previously expressed wishes
relating to a medical intervention by a patient should be taken into account according to article 9 of the Convention.

G. Informed consent in case of minor patients

**Article 6 Biomedicine Convention**

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

According to Slovak legislation a minor patient is any patient who is younger than 18 years of age. Section 9 of the Slovak Civil Code allows minors to execute a legal act that is by its nature adequate to the intellectual and volitive abilities of the minor. However, this provision is not applicable in the context of health care provision, as section 6 of the Act on Health Care of 2004 stipulates that a minor is considered to be incapable to consent with the provision of the health care. Before the Act on Health Care went into force in 2004, minors older than 16 years could consent with the provision of the health care without any intervention of their parents or legal representative if the physician concluded that their mental abilities allowed them to understand the implications of the medical intervention. The draft of the Act on Health Care of 2004 did contain a regulation that was identical to this regulation, but during the legislative process this was criticized by the Ministry of Interior and by the office of the Deputy...

Prime Minister for Minorities and as a consequence of this criticism the regulation was omitted.\textsuperscript{17}

If health care is to be provided to a child, information preceding the consent should be provided to the legal representative, tutor or foster of the under-aged child (hereinafter “legal representative”) (section 6 (1) b)). According to section 6 (5) the informed consent to the medical intervention shall also be given by them. The patient who is incapable of giving his informed consent however, shall participate in the decision making process to the highest possible extent allowed by his abilities. If the informed consent was given by the legal representative, a statement of the person incapable of giving the informed consent shall be recorded in his medical file (section 6 (9)). In spite of the regulation provided for in the first paragraph of section 6, one may conclude that information should be provided to the legal representative as well as to the minor patient depending on his abilities in order to effectuate his participation in the decision making process.\textsuperscript{18}

If the legal representative of the minor patient refuses to give an informed consent, the health care provider can file a motion to a court. The informed consent of the legal representative shall be substituted by the court’s approval to the health care provision. Awaiting the decision of the court, only health care that is necessary to save the patient’s life may be provided (section 6 (6)).

H. Informed consent in case of incapacitated adults

Article 6 Biomedicine Convention

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorization procedure.

The position of the patient who is deprived of the capacity to exercise his rights granted by the Act on Health Care or the patient who has a limited capacity to exercise them, is very similar to the position of a minor patient (see §3 G).

If health care is to be provided to a patient who is deprived of the capacity to exercise his rights granted by the Act on Health Care or to a patient who has a limited capacity to exercise them, information preceding the consent should be provided to the legal representative (section 6 (1) b)). According to section 6 (5) informed consent shall also be given by the representative. The patient who is incapable of giving his informed consent however, shall participate in the decision making process to the highest possible extent allowed by his abilities. If the informed consent was given by the legal representative, a statement of the person incapable of giving the informed consent shall be recorded in his medical file (section 6 (9)).

If the legal representative of the incapacitated adult refuses to give an informed consent, the health care provider can file an application to a court. The informed consent of the legal representative shall be substituted by the court’s approval to the health care provision.
Awaiting the decision of the court, only health care that is necessary to save the patient’s life may be provided (section 6 (6)).

According to section 6 (9) c) an informed consent shall not be required in case of inpatient care if the patient endangers himself or his environment due to a mental illness or due to a disease with symptoms of a mental defect (see §3 D).

§ 4. Right to information about his or her health

**Article 10 Biomedicine Convention**

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

A. Right to information about his or her health as a basic requirement

Slovak health law provides the right to information about his health as a right independent of the right to informed consent. Section 11 is entitled “the rights and obligations of persons in the process of health care provision” and stipulates that each person has the right to be informed about his health condition (section 11 (8) b)).

B. Right not to know

Although the Act on Health Care explicitly provides the right not to be informed within the framework of informed consent (section 6 (3) - see §3 B), the right not to know is not recognized as such by the Slovak health law. As the European Convention on Human Rights and Biomedicine is directly applicable in Slovakia, the right not to know according to article 10 of the Convention should be respected.
C. Therapeutic exception

The Slovak health legislation only contains a therapeutic exception with respect to the access of the patient’s medical records (see below). The third paragraph of section 25 of the Act on Health Care stipulates that the health care provider can refuse the access of the medical file by the patient in the specialized field of psychiatry or clinical psychiatry if this negatively affects his treatment. As a consequence of the wording “if this negatively affects his treatment”, the therapeutic exception is only admitted in the interest of the patient.

If he believes that the access of the medical records has been denied without a legitimate reason, the patient is entitled to file an application to seek court protection (section 25 (4)).

§ 5. Patient rights regarding the medical file

<table>
<thead>
<tr>
<th>Article 10 Biomedicine Convention</th>
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<tbody>
<tr>
<td>1. <em>Everyone has the right to respect for private life in relation to information about his or her health.</em></td>
</tr>
<tr>
<td>2. <em>Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.</em></td>
</tr>
</tbody>
</table>

Patient rights regarding the medical file are extensively regulated in part three of the Act on Health Care concerning the medical file.

A. Right to a medical file

In accordance to one of the initial provisions of the Act on Health Care the maintaining of medical records is an integral part of health care provision (section 4 (5)).

The right of the patient to a medical file is formulated in terms of an obligation for the health care providers in section 18 of the Act on Health Care. The first paragraph of this section stipulates that the
health care provider is obligated to process, provide and enable access to the data of medical records in line with the Act on Health Care and separate regulation. Whoever is provided with or had access to data of a medical record has to ensure its confidentiality and has to ensure its protection against loss or abuse (section 18 (3)).

According to section 19 (1) maintaining of a medical record can be defined as the acquisition, collecting and recording of data. The medical file as a whole is maintained by the patient’s general practitioner. Other attending health care professionals maintain medical records regarding the health care provided by them. Medical records are maintained in a written form or in an electronic form with secured electronic signature (section 20 (1)). Section 20 of the Act on Health Care sets out a whole range of conditions for keeping electronic medical records. However, they are not used in Slovakia due to the costs of keeping such electronic records.19

The health care provider is responsible for securing and archiving the medical file. The provider has to store and protect the medical records in a way to prevent its damage, loss, destruction or abuse within the duration of the prescribed archiving period (section 22 (1)). The patient’s general practitioner has to archive his medical records for the period of 20 years after the death of the patient, whereas other attending medical professionals should archive it for the period of 20 years as from the date of the latest provided health care (section 22 (2)).

B. Contents of the medical file

The Act on Health Care defines in section 2 (6) medical records as a set of data on the health condition of a patient or on the health care and health care related services provided to him. Besides this general formulation, section 19 and section 21 determine the contents of the medical file in a more detailed manner.

According to the second paragraph of section 19 a medical file contains the following data:

- a) personal data of the patient with the intention of identifying the patient and finding out his medical history;
- b) data related to the provision of information and informed consent;
- c) data on the patient’s diseases, on the course and results of examinations, on the treatment and on other significant circumstances connected with the health condition of the patient and the process of health care provision;
- d) data on the scope of provided health care;
- e) data on health care related services;
- f) data on temporary work incapability due to illness or injury and the circumstances significant for appraisal of the capability for performing work;
- g) epidemiological significant circumstances;
- h) identification data of the pertinent health insurance company;
- i) identification data of the provider.

The medical file of a woman who has made a written application for nondisclosure of her identity in connection with childbirth, is considered as a special medical file (section 19 (4)). This kind of medical record will contain the provided health care connected with her pregnancy and delivery. It does not contain personal data which would lead to the identification of the mother. The personal data will be kept separately from the special record together with the written application for anonymous childbirth.

Section 19 (5) stipulates that the health care provider has to maintain the special medical records separately from the medical records of other persons.

According to the third paragraph of section 21 reports in a medical record must be truthful and readable. Such a report in a medical record has to contain the following information:

- a) the date and time of the report;
- b) method of providing information to the patient, content of information, refusal of information, informed consent, refusal of informed consent and withdrawal of informed consent (see also section 6 (9));
c) the date and time of the provided health care (if different from the date and time of the report);
d) the scope of provided health care and health care-related services;
e) results from other examinations if they are a part of the provided health care of which the report is being taken;
f) identification of the attending medical professional;
g) identification of the patient.

If the medical file is maintained in a written form, the identification of the attending medical professional is accomplished by his name, surname, seal stamp and his signature. In the case of an electronic medical file the electronic signature is sufficient (section 21 (2)).

C. Right to access and copy the medical file

i. Right to access the medical file

The health care provider is in accordance with section 18 (1) not only obligated to process and provide the medical file of the patient, but also obligated to enable its access. The first paragraph of section 25 enumerates those persons who have the right to access the patient’s medical file. According to this provision access to the medical records is guaranteed to:

a) the patient himself or a legal representative;
b) a husband or wife, child or parent (or their legal representative) after the death of the patient; in case there is no such person, an adult living together with the patient in time of his death or a relative (or their legal representative) (see below);
c) a person authorized on the basis of a written mandate in accordance with a) or b) with certified signature (notarized) to the extent determined in the mandate;
d) an inspection doctor of a competent health insurance company for the purposes of inspection activities;
e) the Surveillance Authority (the Ministry of Health or a physician and nurse of a self-governing region\(^\text{20}\)) for the purposes of surveillance of health care;

f) an appraisal physician of the social security institution for the purposes of medical appraisal activities upon execution of social insurance and social security of policemen and soldiers in accordance with separate legislation;

g) an advisor established by a court or required to give his expert opinion by the police or by one of the parties in a criminal or civil proceeding; the expert determines the necessary scope of access to the medical file himself;

h) the health insurance company performing individual health insurance for the purpose of inspection activities of provided health care related to insurance payment;

i) the pertinent body of professional organization to the extent of inspection performed by the organization.

Whoever has access to the medical file of a patient pursuant to the Act on Health Care not only has to ensure its confidentiality, but also its protection against loss or abuse (section 18 (3)).

As stated above (see §4 C), the health care provider is allowed to refuse access to a medical file if the patient is provided with the health care in the specialized field of psychiatry or clinical psychiatry and the access to the medical records would negatively affect his treatment (section 25 (3)).

The medical file of a woman who has made a written application for nondisclosure of her identity in connection with childbirth is considered as a special medical record (section 19 (4)). Access to those special medical records is restricted. According to section 19 (5) section 25 is not applicable to those special medical files. Consequently, they will be excluded from all access to the medical records.

There is no specific legal regulation concerning the personal notes of the physician. The patient has no access to them if they are not part of the medical file. Consequently, it is not possible for the patient to have knowledge of their existence.21

A patient has not only direct access, but also indirect access to his medical records. He has the right to give written authorization to a

21 Personal Communication of P. KOVÁČ.
person designated by him to inspect his medical records. The notarized mandate shall determine the extent of accessible data (section 25 (1) c)).

ii. Right to copy the medical file

Each person who has the right to access the medical file also has the right to make extracts or copies to the extent that he has access (section 25 (2)). The Act on Health Care does not contain any provisions with regard to the payment for such an extract or copy. The question of who bears the costs is solved on ad hoc basis. Although a fee for allowing access to the medical file is not required by health care providers, they may require a fee for providing copies of the file. 22

The Act on Health Care defines in the first paragraph of section 24 the possible contents of an extract of the medical file. An extract may contain the following:

a) personal data of the patient with the intention of identifying the patient and finding out his medical history;

b) identification data of the pertinent health insurance company;

c) identification data of the provider;

d) a chronological description of the development of the patient’s health condition;

e) an up to date review of treatment;

f) data necessary for further health care provision;

g) date of issue of the extract and the identification of the issuing medical professional.

According to the second paragraph of section 24 the general practitioner is obligated to provide an extract of the medical record to other medical professionals without undue delay. When he is sending a patient for further health care provision to a specialist, he has to provide the extract on his own initiative. Specialists have a corresponding duty towards general practitioners (section 24 (3)). Moreover, any provider of health care is obligated to provide -upon written request- an extract for the medical file to:

a) a physician of a territorial military administration for the purpose of regular enlistment;
b) a competent authority for the purpose of social assistance, state social allowances or employment services in accordance with separate regulations;
c) a labor inspectorate and other surveillance authorities in accordance with separate regulations for the purposes of work injury or occupational disease investigation;
d) the competent authority for the purposes of international adoption;
e) persons entitled to access the medical records if the extent of the request does not exceed the extent to which they have access.

iii. Post mortem access by relatives

According to section 25 (1) b) a husband or wife, a child or a parent (or their legal representative) has the right to fully access the medical file of the patient after his death. In case there is no such person, the right to access the medical file shall be exercised by an adult person living with the patient at the time of his death or a relative (or their legal representative). The person who is entitled to access the medical records after the patient’s death shall also have the right to make extracts or copies from the medical file (section 25 (2)).

D. Right to correction, erasure and/ or demolition

In accordance with section 21 (4) of the Act on Health Care correction of a report in the medical file is accomplished by a new entry consisting of the correction date, the corrected information and the identification of the attending medical professional who corrected the entry. Only the author of the original entry is entitled to correct his report. It is specifically required that the original entry must remain legible after the correction.
§ 6. Right to medical secrecy/ confidentiality

The Act No. 578/2004 on health care providers, medical workers, professional organizations in the health service and on the amendment and supplementing of certain laws stipulates in section 80 (2) that all health care providers are obligated to uphold confidentiality of all facts learned by them as a result of their occupation and the delivery of health care to the patient. According to section 80 (3) this obligation to uphold confidentiality could be waived by the person whom these facts concern or by the competent issuing authority at the request of criminal authorities and the courts. The latter allows the waiving of the obligation even against the patient’s will. According to KOVÁČ however, this situation is virtually hypothetical as a patient who is the victim of a crime has natural interest to prosecute the perpetrator and therefore usually consents to the provision of the facts concerning his health to the police and courts. 23

The Act on Health Care assures the right to professional secrecy as a patient right. According to section 11 (8) g) each person is entitled to confidentiality of all information regarding one’s health condition and all information related to the health condition, unless stipulated otherwise by a separate regulation. In addition to this provision, section 18 (3) determines that whoever is provided with the medical records or had access to them is obligated to uphold confidentiality and has to ensure its protection against loss or abuse.

According to section 22 (3) the health care provider has to secure the access to the medical file for the attending physician and medical professionals to the extent that it is necessary. According to the second paragraph of section 24 the general practitioner is obligated to

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provide an extract of the medical record to other medical professionals without undue delay. When he is sending a patient for further health care provision to a specialist, he has to provide the extract at his own initiative. Specialists have a corresponding duty towards general practitioners (section 24 (3)). The Act on Health Care Providers stipulates that the obligation to uphold confidentiality is not breached by the forwarding of the patient’s medical file between physicians (section 80 (4)). According to section 80 (5) the confidentiality is also not infringed upon by informing a medical worker, if the scope of the provided information does not exceed the framework of information that is essential for the medical worker in order to be fully discharged of his tasks or by informing members of chambers when they exercise their powers and to the extent that is provided by the Act on Health Care Providers.\textsuperscript{24}

\textbf{§ 7. Right to privacy/ protection of private life}

\begin{center}
\textbf{Article 10 Biomedicine Convention}
\end{center}

\begin{quote}
1. \textit{Everyone has the right to respect for private life in relation to information about his or her health.}
\end{quote}

Section 2 of the Slovak Constitution which is entitled “Fundamental Human Rights and Freedoms” contains several provisions with regard to the right to privacy. According to article 16 (1) the right of every individual to integrity and privacy shall be guaranteed. This right may only be restricted in case this is specifically provided for by law. In addition to this provision, everyone has in accordance with article 19 (2) the right to be free from unjustified interference in his or her private and family life. Furthermore, article 22 (1) of the Constitution determines that secrecy of letters, other communications and written messages delivered by post and the secrecy of personal data shall be guaranteed.

\textsuperscript{24} According to section 48 of the Act on Health Care Providers a chamber is a self-administrating professional organization that has nationwide jurisdiction for the territory of the Slovak Republic.
Privacy and secrecy of the patient’s personal data and any data related to his health condition is one of the basic preconditions for the provision of health care.\textsuperscript{25} However, the Act on Health Care does not provide for the right to privacy or the right to the protection of private life as a patient.

A. Processing of data concerning health

The processing of personal data and the protection of the rights of data subjects are regulated by the Act No. 428/2002 Coll. on Protection of Personal Data. According to section 3 of this Act personal data is defined as any information related to an identified or identifiable natural person, who can be identified -directly or indirectly- in particular by reference to qualities that are specific to his physical, physiological, psychic, mental, economic, cultural or social identity. However, section 8 of the Act on Protection of Personal Data considers any data related to the health condition of a person as special data. This kind of special data can only be processed if the data subject gives his written consent to their processing or if a special law allows it (section 9).

B. Right to access and right to receive a copy

The Act on Protection of Personal Data contains in section 20 several provisions concerning the rights of the data subject. According to subsection a) of the first paragraph of this provision the data subject is entitled to request information -upon written application- about the state of processing of his personal data in a generally intelligible form. The controller of the data subject’s personal data shall notify him in writing at the latest within 20 days from the receipt of the request (section 21 (3)) and he shall satisfy the request by providing the requested information (section 21 (1)).

The data subject also has the right to request -upon written application- a copy of his personal data in a generally intelligible form (section 20 (1) c)). The controller of the data subject’s personal data shall notify him in writing at the latest within 20 days from the receipt

of the request (section 21 (3)). He shall provide the information free of charge, except for a fee of which the amount does not exceed the material costs of making the copies, providing technical carriers and sending the information to the data subject, unless a special Act provides otherwise (section 21 (2)).

C. Right to correction, erasure and/or demolition

The Act on Protection of Personal Data guarantees the right to request -upon a written application- the rectification of inaccurate, incomplete or not updated information (section 20 (1) d)). The data subject is also entitled to request the demolition of his personal data in compliance to section 13 of the Act (section 20 (1) e)). According to this provision the personal data shall be destroyed after the purpose of processing is fulfilled, unless a special Act such as the Act on Health Care stipulates a time limit (section 13 (1) and (3) a)). The Act on Health Care determines that the patient’s medical file that is maintained by a general practitioner will be archived for the period of 20 years after the death of the patient. The medical records that are maintained by other health care professionals will be archived for the period of 20 years as from the date of the latest provided health care (section 22 (2)). Furthermore, the data subject has the right to request the demolition of his personal data that was processed in an unlawful manner (section 20 (1) f))

The second paragraph of section 20 of the Act on Protection of Personal Data stipulates that only the right to correction (section 20 (1) d)) and the right to request the demolition in compliance to section 13 of the Act (section 20 (1) e)) may be restricted, if such a restriction results from a special Act or if exercising the rights would infringe upon the protection of the data subject or the rights and freedoms of others.
§ 8. **Right to complain and to compensation**

A. **Right to complain**

**Article 23 Biomedicine Convention**

*The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.*

The right to complain has been one of the most discussed patient rights in the past 2 years in Slovakia. It is a well-known patient right and it is used very often in Slovakia. The patient can file his complaint with several entities.

A patient who is not satisfied with the provision of health care can file a complaint with the management of the respective facility. The complaint will be investigated by the management and the patient will receive information about the result of the investigation. Complaints regarding the professional or ethical behavior of the health care provider may also be filed with the competent professional chamber.

Most of the patients’ complaints are filed with the Health Care Surveillance Authority. The Health Care Surveillance Authority is an independent legal entity which was established by the Act No. 581/2004 Coll. on health insurance companies, health care supervision and on the amendment and supplementing of certain laws. It is entrusted with the performance of surveillance over health insurance companies, over public health insurance and over the provision of health care (section 18 (1) a) and b) of the Act on Health Insurance Companies). The Authority investigates the patients’ complaints and notifies them of the results of the investigation. It may initiate a procedure that would lead to the cancellation of the permit for the health care facility or the cancellation of the license of the health care professional.

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The Ministry of Health supervises the health care provision in accordance with section 45 k) of the Act on Health Care. Consequently, patients can file complaints and petitions with the Ministry. As permit issuing authority, the Ministry of Health and the self-governing region have the power to investigate and eventually sanction a breach of obligation when it has jurisdiction over the providers, such as the duty to display a price list on a visible place or a list of health insurance companies that have signed a contract with the provider.

The patient who is dissatisfied with the outcome of his complaint has the possibility to appeal against the decision or to file the same complaint with a different authority.

The Act on Health Care stipulates in the fourth paragraph of section 11 that each person who believes that his rights or legally protected interests were infringed upon as a consequence of failure to equal treatment is entitled to seek court protection. The person may not be persecuted nor punished in any other way for lodging a complaint, an accusation or starting a lawsuit against another person, medical professional or provider (section 11 (3)). A similar provision can be found in section 11 (5). According to this provision a health care provider may not persecute nor disadvantage the person who claims his entitlements in accordance with the Act on Health Care.

B. Right to compensation

Article 24 Biomedicine Convention

*The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.*

Slovak health care legislation does not contain any specific provisions concerning the right to compensation. Consequently, the general provisions with regard to civil liability of the Act 40/1964 Coll. the Civil Code as amended will apply. The Civil Code itself does not contain special regulations related to the liability for the provision of health care as such. According to section 415 of the Civil Code everyone is obliged to act in a way that will not cause any damage to another person’s health, property, nature and living environment.

Everyone is responsible for the damage that was caused due to a breach of legal obligations (section 420). Civil liability in Slovakia is based on culpability and the notion of presumed liability. Anyone who can prove that the occurred damage was not caused by him can not be held liable. These general principles apply without any exception to the liability of health care providers.

The Civil Code contains also provisions regulating special types of liability such as section 421 a) concerning the liability for damage caused by the nature of a device or item used for fulfilling a legal obligation. This section specifically stipulates that such liability includes also the provision of health care. However, there are dissenting opinions on the applicability of this provision. The wording of section 421 a) does not clarify whether it applies to the provision of health care as such or only to situation where devices are used.

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IV. RIGHTS OF USERS OF GENETIC SERVICES

§ 1. Introductory remark

Genetic testing in Slovakia is mainly regulated by the legal framework that applies to health services as a whole, as there is at present no specific legal framework concerning genetic testing in Slovakia. Consequently, the regulations on patient rights are *mutatis mutandis* applicable as rights of users of genetic services.

The European Convention on Human Rights and Biomedicine has in accordance with the Slovak Constitution a superior force to any national legislation and is directly applicable in Slovakia (see III §1). As a result of this direct applicability, the provisions of the Convention related to genetic services can be applied.

A. Right to informed consent

The right of a patient to consent to diagnostic procedures (such as genetic tests) is one of the basic patient rights in Slovakia. According to section 6 (4) of the Act on Health Care an informed consent is a proven consent with medical interventions preceded by information to the health care provision or a proven consent preceded by a refusal of that information. The informed consent shall be given by the patient or by his legal representative if the patient is incapable to give his informed consent. Whoever is entitled to give the informed consent shall also be entitled to withdraw it freely at anytime (section 6 (7)). The Act on Health Care also acknowledges the right to refuse a medical treatment, unless the health care is even allowed without the patient’s informed consent in accordance with section 6 (8) (section 11 (8) d)).

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B. Right to information

Slovak law provides the right to information about his health status as a right independent of the right to informed consent. According to section 11 (8) d) of the Act on Health Care each person is entitled to be informed of his health condition.

Although the Act on Health Care explicitly provides the right not to be informed within the framework of informed consent (section 6 (3)), the right not to know is not recognized as such by the Slovak health law. As the European Convention on Human Rights and Biomedicine is directly applicable in Slovakia, the right not to know according to article 10 of the Convention should be respected.

C. Right to privacy

The Act on Health Care does not provide for the right to privacy or the right to the protection of private life as a patient. The right to privacy is guaranteed by the Slovak Constitution.

The processing of personal data and the protection of the rights of data subjects are regulated by the Act No. 428/2002 Coll. on Protection of Personal Data.

§ 2. Prohibition of discrimination on grounds of genetic heritage

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*Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited*

Although there is -besides the directly applicable article 11 of the Convention- no explicit prohibition of discrimination on grounds of genetic heritage, the general principle of non-discrimination is guaranteed by several provisions. The Constitution of the Slovak Republic stipulates in article 12 that fundamental rights shall be guaranteed by the Slovak Republic to everyone regardless of sex, race, color, language, belief and religion, political affiliation or other
conviction, national or social origin, nationality or ethnic origin, property, descent or any other status. No one shall be discriminated against or favored on any of these grounds. Furthermore, the Act No. 365/2004 Coll. (or the Antidiscriminatory Act) determines the principle of non discrimination in a very general manner by stating that discrimination within the provision of health care is -amongst others- prohibited.

§ 3. Use of predictive genetic tests

**Article 12 Biomedicine Convention**

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

No explicit regulations on the use of predictive genetic tests could be found in Slovak medical law. The lack of national legislation however does not mean that the use of predictive genetic tests is not regulated since article 12 of the Biomedicine Convention is directly applicable.
V. CONCLUDING REMARKS


2. According to the Constitution of the Slovak Republic the Convention on Human Rights and Biomedicine has a superior force to any national legislation and is directly applicable in Slovakia.

3. The Slovak Constitution, the health care reform package of six Acts from 2004 and subsequent legislation create a comprehensive legal framework of patient rights in Slovakia. However, patient rights as such are laid down in the Act No. 576/2004 Coll. on health care and health care-related services and on the amendment and supplementing of certain laws as amended.

4. The right of a patient to informed consent is one of the basic patient rights in Slovakia. The informed consent shall be given by the patient or by his legal representative if he is incapable to give his informed consent. The information that has to precede the consent should be given in a comprehensible, understandable manner without any restraint, with sufficient time and with the possibility to opt freely for informed consent. The information should also be given in a way that is adjusted to the intellect, the will and the health condition of the patient.

5. Previously expressed wishes relating to a medical intervention are not regulated in Slovak health law. As the European Convention on Human Rights and Biomedicine is directly applicable in Slovakia, the previously expressed wishes relating to a medical intervention by a patient should be taken into account according to article 9 of the Convention.

6. Slovak law provides the right to information about his health status as a right independent of the right to informed consent. The right not
to know is not recognized as such by the Slovak health law. As the European Convention on Human Rights and Biomedicine is directly applicable in Slovakia, the right not to know according to article 10 of the Convention should be respected.

7. The maintaining of a medical file is an integral part of health care provisions. The health care provider has not only to process and provide the medical file of the patient, but also to enable its access. The Act on Health Care enumerates those persons who have the right to access the patient’s medical file. The health care provider is allowed to refuse access to a medical file if the patient is provided with the health care in the specialized field of psychiatry or clinical psychiatry and the access to the medical records would negatively affect his treatment.

8. The processing of personal data and the protection of the rights of data subjects are regulated by the Act No. 428/2002 Coll. on Protection of Personal Data.

9. Slovakia has no specific law on genetic testing. The regulations on patient rights are mutatis mutandis applicable as rights of users of genetic services. As a result of its direct applicability, the provisions of the Convention related to genetic services are applicable.
VI. BIBLIOGRAPHY


