



Patients' Rights in the European Union

Content

Introduction	p. 2
Human Rights at the basis of Patients' Rights	p. 3
Patients' Rights	p. 5
Overview Patients' Rights in EU Member States	p. 6
Austria	p. 7
Belgium	p. 7
Bulgaria	p. 8
Cyprus	p. 9
Czech Republic	p. 9
Denmark	p. 10
Estonia	p. 11
Finland	p. 11
France	p. 12
Germany	p. 13
Greece	p. 13
Hungary	p. 14
Ireland	p. 15
Italy	p. 15
Latvia	p. 16
Lithuania	p. 17
Luxembourg	p. 17
Malta	p. 18
The Netherlands	p. 19
Poland	p. 19
Portugal	p. 20
Romania	p. 21
Slovakia	p. 21
Slovenia	p. 22
Spain	p. 22
Sweden	p. 23
United Kingdom	p. 24
Sources	p. 25

Introduction

This document aims to give an overview of the rights of patients throughout the European Union (EU). As patients' rights encompass multiple and diverse issues it will not be possible to include all different aspects within this single document. However, this document provides a solid framework regarding patients' rights in Europe and does so in several ways. First it places the rights of patients within the framework of human rights. As the development of patients' rights stems directly from the progression of the human rights it is important to focus on the legislation and commitments that came out of this. Secondly it will give an overview on the place of patients' rights within the overall European legislation and initiatives. Finally an overview on various topics regarding patients' rights of each EU member state is made.

The development of patients' rights is an ongoing process. This document therefore provides the status of patients' rights at the time of writing (end of 2009).

Human Rights at the basis of Patients' Rights

Human rights are inherent in every human being. The term 'human rights' refers to those rights that have been recognised by the global community in the *Universal Declaration of Human Rights (UDHR)*, adopted by the *United Nations (UN)* Member States in 1948¹, and in other international legal instruments binding on States. 'Human rights' is not only a generic term representing a symbol of our contemporary society but are also the reflection of a common perception on human values.

The UDHR recognises the "inherent dignity" and the "equal and unalienable rights of all members of the human family". And it is on the basis of this concept of the person, and the fundamental dignity and equality of all human beings, that the notion of patients' rights was developed. In other words, what is owed to the patient as a human being, by physicians and by the state, took shape in large part thanks to this understanding of the basic rights of the person.

The UDHR is focussed upon the universal rights regarding all human beings. This universal nature of the document has been reaffirmed by the UN in 2005². The promotion and protection of human rights on a European level were inspired by this declaration. The *Council of Europe* was established in 1949 to promote the rule of law, human rights and democracy. The first European treaty to protect human rights is the *European Convention for the Protection of Human Rights (ECHR)*. It was signed in Rome, on 4 November, 1950 and entered into force on September 3, 1953. To ensure the respect of this Convention, the *European Court of Human Rights* was established. This Court plays a fundamental role in the application of the ECHR.

Other treaties and bodies have been established at the European level to complete this document:

The European Social Charter: adopted in 1961 and monitored by the European Committee of Social Rights, guarantees economic, social and cultural rights, such as the rights to housing, health, education, employment, social protection, movement of persons and non-discrimination. It was revised in 1996. An additional Protocol to this Charter entered into force in 1998 providing an opportunity for workers' group and NGOs to lodge collective complaints.

European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment: adopted in 1987 and amended by two Protocols afterwards. This Convention is monitored by the Committee for the Prevention of Torture.

Framework Convention for the Protection of National Minorities: is the first binding international treaty to offer protection specifically for minorities, was adopted in 1955 and entered into force in 1998.

European Commission against Racism and Intolerance: was set up in 1993 to fight racism, xenophobia, anti-Semitism and other forms of intolerance.

¹ The General Assembly of the United Nations, December 10, 1949. *The Universal Declaration of Human Rights*.

² Resolution adopted by the General Assembly of the United Nations, A/RES/60/1: 2005 World Summit Outcomes, 24 October 2005, IV. Human Rights and the rule of law, §120, p.27.

The Commissioner for Human Rights: was established in 1999. To promote human rights education and awareness of human rights, to identify areas of laws that fail to recognize human rights to a full extent and human rights laws that are not fully implemented and to promote a respect for and enjoyment of human rights in Council of Europe Member States.

The Charter of Fundamental Rights of the European Union: was adopted in Nice, in December 2000 as a political declaration. It contains 54 articles mainly collected from the European Convention on Human Rights. The Lisbon Treaty recognises the Charter in Art.6 TEU and makes it legally binding³.

³ European Community. December 13, 2007. *Treaty of Lisbon amending the Treaty on European Union*. In force: December 1, 2009

Patients' Rights

Several European institutions and organisations have contributed to the development and progress of patients' rights. The term 'patient' is most often used in connection with health. Health relates to the state of physical, mental and social well-being. This definition, used by the World Health Organisation⁴, involves more than just the absence of disease or infirmity. Ensuring the respect of human rights has a direct impact on health and well-being and enforced the importance of specific patients' rights.

The European Union Health Strategy is to ensure a high level of health protection across all policies and actions. This commitment was set out in Article 3 of the Amsterdam Treaty, and reiterated in the public health article, Article 152. In the Treaty of Lisbon this will be Article 168.⁵ This article serves as the most prominent legal basis for patients' rights within the EU legislation and contains the first direct references to social insurance systems, opening the way for EU actions in this field. But this article also guaranteed the competence on organisation and delivery of healthcare to Member States. The European Commission (EC) recognised the need for patient involvement in health-related policy-making in its White Paper "*Together for Health: A Strategic Approach for the EU 2008-2013*"⁶, which claims that healthcare is becoming increasingly patient-centred. Community health policy needs to begin with patients' rights, which include participation and influence on decision-making. Involving patients in the decision-making process helps to ensure that policies are implemented which support patients' and their carers' needs and capabilities.

Another important document concerning patients' rights is the "*European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine from 1997*"⁷, stipulating the legal principles which are binding on the field of medicine and biology. Together with the European Convention on Human Rights, it is one of the leading treaty documents passed by the Council of Europe. Since 1997, the Member States of the Council of Europe started the process of ratification that commits them to make their laws compatible with the principles and requirements of this document. Up till now 24 Member States of the Council of Europe have ratified this document.

Besides the EU and Council of Europe other organisations have focused on the strengthening of patients' rights. In 2002, the organisation *Active Citizenship Network*, in cooperation with other citizens' organisations drafted a "*European Charter of Patients' Rights*"⁸ to strengthen and bring greater awareness concerning patients' and citizens' rights. The Charter specifies fourteen patients' rights that aim to guarantee a high level of human health protection.

⁴ Preamble to the Constitution of the World Health Organisation as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (*Official Records of the World Health Organisation, no. 2, p. 100*) and entered into force on 7 April 1948.

⁵ European Union. *Consolidated Version of the Treaty on the Functioning of the European Union*. Official Journal of the European Union. 2008. Title XIV, C115/122, p.76.

⁶ European Commission, Brussels, October 23, 2007 COM (2007) 630 final. *Together for Health: A Strategic Approach for the EU 2008-2013*. p.4.

⁷ Council of Europe. *Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine CETS No.: 164*. April 4, 1997.

⁸ Active Citizenship Network. (2002). *The European Charter of Patients' Rights*.

Overview of Patients' Rights in the European Union Member States

Although these initiatives and documents have stimulated the development of patients' rights, the EU Member States (MS) currently do not have a common patients' rights legislation. Patients' rights throughout the EU vary from one country to another for various reasons. The most prominent one is that the Member States hold the competence in the health domain. Furthermore different health care systems, procedures, cultures and priorities add to the variety of the legislation.

An example of different legislation would be that some countries have a single law or act defining the rights of patients, whereas others use multiple pieces of legislation. The approach differs also on the focus as some MS putting more emphasis on the rights of patients and others more on the specific obligations of the healthcare providers.

This overview is an attempt to provide a framework concerning patients' rights on the legislation and policies of the EU MS. It looks in particular at the rights of patients relating to:

- Right to informed consent
- Right to information concerning own health
- Right to medical records
- Right to privacy
- Right to complain and compensation

Austria

Austria has several documents concerning patients' rights. There is a Patients' Charter (2002); a Federal Physicians Law (1998); a Federal Hospitals Act (1957) and the Federal Act concerning the Protection of Personal Data (2000).

Right to informed consent: Patients can only be treated with their informed consent. If the patient is not able to do so, his/her representative may give his/her consent (Art. 17 of the Patients' Charter).

Right to information concerning own health: Patients have the right to be informed about all possible treatments and alternatives. Furthermore they are entitled to have their questions answered in a way that is comprehensible (Art. 7 of the Patients' Charter).

Right regarding the medical records: The patient has a right to access his/her medical records at any time.

Right to privacy: Art. 9 of the Patients' Charter indicate that the right of privacy of patients should be guaranteed. Furthermore, the Federal Physicians Law also covers this part, as doctors need to respect the confidentiality of their patients.

Rights to complain and compensation: Patients have a right to complain, this often is done by means of a representative of a patient organisation. The Ombudsman covers the complaints of patients. Furthermore patients can start legal procedures against the healthcare provider in case of malpractice or infringement.

Belgium

The rights and duties of physicians and patients are regulated in the "Law on the rights of patients" of August 22, 2002⁹.

Right to informed consent: Informed consent must be given by the patient before any treatment may start. This consent only lasts as long as the medical intervention. More explicitly Art. 8.4, third paragraph states that neither refusal nor withdrawal of consent shall end the right to high-quality care. In other words, refusal by the patient to undergo a medical treatment does not terminate the legal relations between the patient and the physician.

Right to information concerning own health: Art.7 makes clear that the patient has the right to receive all information concerning his/her state of health. In exceptional cases, the health professional may withhold information about the patient's state of health if disclosure would cause great harm to the patient; this is called the therapeutic exception.

Right regarding the medical records: Art.9, paragraph 1, states that the patient has the right to a medical record. The law however does not give a specific definition of a medical record. Patients have the right to access their own medical records (paragraph 2).

⁹ Belgium Ministry of Social Affairs, Health and Environment. *Law on the rights of patients*. August 22, 2002.

Right to privacy: The subject of privacy is not covered in this law specifically, as this is already embedded within the Belgian Constitution (Art.22¹⁰ the right of privacy). A distinction is made here between the right of privacy of the patient (privacy of data regarding health and protection) and the obligation of the physician to medical secrecy (protection of confidence regarding the information the patient shares with the physician). However, the Law on patients' rights does cover the subject regarding the protection of intimacy regarding the patient in Art. 10 (paragraph 1).

Rights to complain and compensation: The patient can register a complaint with the competent ombudsperson's office. The responsibilities of the ombudsperson's office are established in Article 11, 2.

Bulgaria

Besides the Constitution (Art. 52 and 57)¹¹, patients' rights are protected in several acts such as the Human Medicinal Drugs and Pharmacies Act (1995); the Health Insurance Act (1998); the Act for professional associations of physicians and dentists (1998); the Food Act (1999) and the Health Act (2004). The Health Act of 2004¹² is however the most important one as it regulates the status, rights and obligations of citizens in healthcare.

Right to informed consent: Art. 52 of the Bulgarian Constitution states that in order to obtain the informed consent, the physician in charge of the treatment shall inform the patient about the procedures and consequences of the treatment. No one shall be subject to forced medical treatment or sanitary measures except in circumstances established by law.

Right to information concerning own health: The physician is obliged to inform the patient about his/her health condition and the need for treatment. This right is embedded within the right of informed consent.

Right regarding the medical records: Specific rules on patients' rights regarding medical records can be found in the Health Act (2004) under Section V, Art. 27 that states that health information shall include the personal data related to the health condition, the physical and mental development of individuals, as well as any other information contained in medical prescriptions, instructions, protocols, certificates and other medical documentation. General rules can be also found in the Personal Data Protection Act.

Right to privacy: Confidentiality concerning the state of health of patients is made certain in the Health Act under Art 28 (paragraph 3). Furthermore, the Code of Professional Ethics also contains the obligation of medical secrecy.

Right to complain and compensation: The Health Act of 2004 does not lay down special authorities and procedures for defence of patients. The claims for liability or failure of obligations can be grounded on the Act on the Obligations and Contracts, section III (Effects of Obligation). Art. 79 to Art. 87¹³ contain provisions regarding this procedure.

¹⁰ De Belgische Grondwet, Artikel 22 Wet van Privacy, Gecoördineerde tekst, 1994.

¹¹ Constitution of the Republic of Bulgaria adopted on 18 May, 1971

¹² Republic of Bulgaria. National Assembly. *Health Act*. 2004.

¹³ Republic of Bulgaria. National Assembly. *Obligations and Contracts Act*. 1993.

Cyprus

Cyprus created the “Law on the protection of the rights of patients and related issues” in 2005¹⁴. This act especially focuses on the quality of health, the choice of doctors / institutions, and the integrity of the patient.

Right to informed consent: Art.11 (1) of the patients’ rights Act of 2005 states that a patient’s consent must be given before starting any medical treatment.

Right to information concerning own health: According to Art.10, the patient shall have the right to complete medical information. This includes the diagnosis and the prognosis of the patient medical condition. The physician may use the therapeutic exception (Art.10.3).

Right regarding the medical records: The healthcare service provider has a duty to keep medical records containing all relevant information of the patient (Art.17). The patient also has the right to access these records. The therapeutic exception does also apply for medical records.

Right to privacy: Art. 15 explicitly states that all information about the patient’s medical condition (including all personal data) shall be kept confidential. This is also the case even after the patient dies.

Right to complain and compensation: The right to complain is not directly regulated in the Patients Rights Act of 2005. Article 22 (1) does provide a Patients’ Rights Officer who handles complaints or sends them to the Complaints Examinations Committee (Article 23). No explicit regulations on the right to compensation are included.

Czech Republic

The legislation of the Czech Republic concerning patients’ rights is fragmented. Some of the main basic patients’ rights are laid down in the Act number 20/1966 on Healthcare.¹⁵ The problem is that this Act is outdated and does not cover all aspects of patients’ rights. In 1992 the Code of Ethics and Patients’ Rights; and the Ethical Code of Physician of the Czech Medical Chamber were created, however both of them are not legally binding.

Right to informed consent: Art. 23 of the Healthcare Act states that the patient’s agreement is necessary before the treatment may be implemented. The patient should be informed in an appropriate manner about the illness and about the necessary procedures.

Right to information concerning own health: Czech law does not regulate the right to information to patients as a specific and separate right. There is also no legislation available concerning the therapeutic exception. The Ethical Code of the Czech Medical Chamber recognizes the possibility but the decision is up to the physician.

¹⁴ Law N° 1(I)/2005 The Safeguarding and Protection of the Patients' Rights of 7 April 2005. From “*Patients Rights in EU, Cyprus*”. Goffin, T. (2005).

¹⁵ Act 20/1966 Coll. March 17, 1966. on Care of People’s Health.

Rights regarding the medical records: All healthcare establishments are obligated to keep medical files of their patients. This has been laid down in Art.6 of the Code of Ethics and Patients' Rights.¹⁶

Right to privacy: Each healthcare professional has to maintain confidentiality about all the facts he/she was informed about in relation to the exercise of his/her occupation. This right is combined with the right regarding the medical records. Thus also the same legislative document applies.

Right to complain and compensation: There are no specific procedures concerning this right. If the patient is not satisfied, he/she has several possibilities according to the nature of the complaint. In the case of dissatisfaction with the settlement of complaints the patient can turn to the Ombudsman (as stated in the Healthcare Act). A damage resulting from health services is compensated according to the rules in the Civil Code which does not contain special provision on the liability when providing health services.

Denmark

Approved by the parliament on 2005, and put into force on 1 January 2007, Denmark has now one main Health Act, Law No. 546 of 24 June 2005,¹⁷ which covers most of the patients' rights. Previous to this law, Denmark had several different legislative document regarding patients' rights, including: the Law No. 482 of 1 July 1998 on patients' rights; the Act of Abortion; the Act on Assisted Reproduction; and the Act on Transplantation. The Health Law unites these separate laws in one single document.

Right to informed consent: The Health Act 2005 (Art. 15) provides the rights of patients to be included in the involvement of decisions made concerning their health. This includes aspects such as informed consent. Therefore no treatment may be initiated without the informed consent of the patient, unless otherwise established by law or regulation. Furthermore 'minor patients' who have attained the age of 15 are considered to be capable to provide informed consent. Parents must however be informed and be included in the decision-making process.

Right to information concerning own health: Danish law does not regulate the right to information as a separate right and includes this in the overall rights of involvement of patients as described in the informed consent part. The therapeutic exception is illegal since 1998.

Right regarding the medical records: The Medical Practices Act contains a provision regarding the duty of physicians to keep medical records of their patients. A healthcare provider may forward information regarding the history of the illness, the cause of death and the way of death of a deceased patient to the nearest relatives, when this is not considered being against the wishes of the deceased.¹⁸

Right to privacy: The Danish Constitution already provides the protection of privacy in Section 71. Furthermore, a patient has a right to confidentiality from healthcare providers

¹⁶ Code of Ethics and Patients' Rights. approved on 25.2.1992 by the Central Ethics Committee of the Czech Ministry of Health.

¹⁷ Law No. 546. *Health Act*. 24 June 2005.

¹⁸ Denmark, Patients' Rights regarding medical file.

regarding information received or implied during the performance of their profession. The Health Act however does indicate that hospitals are allowed to inform the patient's general practitioner about the treatment provided by the hospital without the explicit consent of the patient.

Right to complain and compensation: Patients' complaints are gathered centrally in one organisation, the Patient's Complaint Board. Patients may claim damages in connection with treatment through the Patient Insurance Scheme, which was set up in 1992. Art. 20 of the Healthcare Act regulates that compensation can be demanded under specific circumstances.

Estonia

The rights and obligations of patients are laid down in the Law of Obligations Act 2001 which entered into force on 1 July 2002.¹⁹ Instead of focussing on the obligations of the healthcare providers, this Act specifically grants the patient clearly defined rights.

Right to informed consent: Estonian law states that informed consent is required. Medical actions may thus only be done when the patient gives his/her consent.

Right to information concerning own health: This right is a part of the right to informed consent. Furthermore there is no provision in the Estonian law regarding the therapeutic exception.

Right regarding the medical records: A healthcare provider is obligated to document all health services provided to the patient. However there are no legal provisions regarding the contents of the medical file.

Right to privacy: The obligation to respect medical secrecy is laid down in the Estonian Criminal Code. The Law of Obligations Act 2001 contains the obligation to respect the confidentiality. Providers of healthcare services shall maintain the confidentiality of information regarding the identity of patients and their state of health.

Right to complain and compensation: Independent review of complaints of patients and compensation for damage due to malpractice is only possible through the court system, which is very complex and time consuming.

Finland

The most important piece of legislation is the Act on the Status and Rights of Patients (No.785/1992).²⁰ This law is also the first patients' rights act in the world and regulates several rights of patients, such as the right to information, the right to self-determination, the maintenance of patient records, etc. However, more Acts are still relevant, such as the Act on

¹⁹ Law of Obligations Act, General Part of the Civil Code Act, passed 5 June, 2002.

²⁰ Ministry of Social Affairs and Health. No. 785/1992. Act on the Status and Rights of Patients. 17 August, 1992.

the Status and Rights of Social Welfare Clients (No.812/2000) (similar to act No.785/1992) and the Act on Patients Injuries (No.585/1986).

Right to informed consent: Section 6 of the Act on the Status and Rights of Patients, which provides the self-determination of patients states that the patient has to give consent before medical treatments can start. If the patient refuses a certain treatment, he/she still has the right to medical care.

Right to information concerning own health: A patient shall be given information about his/her health condition, the treatment, alternative medical procedures and their effects. This may include third party persons, with permission of the patient as is stated in Section 9. The therapeutic exception is allowed.

Right regarding the medical records: Healthcare professionals shall record in patient documents the necessary information as is laid down in Section 12.

Right to privacy: Section 8 of the Constitution states that detailed provision on the protection of personal data shall be prescribed by Act of Parliament: patients must be treated in such a way that their human dignity is not violated and that their conviction and privacy are respected.

Right to complain and compensation: All healthcare establishments have a patient Ombudsman. A patient Ombudsman informs the patients of their rights and assists them as necessary in submitting an objection or complaint (Section 11). A complaint in treatment can be submitted to the relevant State Provincial Office. Compensation can be paid for bodily injuries if there is a causal relation between the injury and the healthcare treatment.

France

Patients' rights are laid down in the Act No. 2002-303 of 4 March, 2002.²¹ Furthermore in 2005, Act No. 2005-370 concerning patients' rights and the end of life came into force. Both these acts cover a wide range of patients' rights in France.

Right to informed consent: Art. 11 of the Code of Public Health has inserted a number of provisions in the Code of Public Health that stipulate that informed consent of the patient is required before any medical treatment can be started.

Right to information concerning own health: Art. L.1111-2 of the Code of Public Health states that everyone has the right to be informed about their medical condition. However, this right only exists in connection to the right to give informed consent.

Right regarding the medical records: Art. L. 1111-7 of the Code of Public Health provides for everyone the right to access the data concerning their health which is kept in a medical file by healthcare providers or healthcare institutions.

²¹ Loi n°2002-303. *relative aux droits des malades et à la qualité du système de santé*. du 4 mars 2002.

Right to privacy: Art. L. 1110-4 of the Code of Public Health prescribes that every patient has the right for his/her privacy to be respected and the right that the data concerning him/her is kept secret.

Right to complain and compensation: Art. L. 1112-3 of the Code of Public Health states that every healthcare service has a committee for the quality of healthcare. It is at this committee that patients can express their complaints. There is furthermore a strict liability in some cases and a compensation mechanism for serious treatment accidents, under the principle of national solidarity.

Germany

Germany does not have any specific legislation concerning patients' rights. It does have the Constitution (including some general Articles related to patients' rights), a Charter of the Rights of Patients (1999), Federal Law on Data Protection (1990), the Charter of Rights of Patients deprived of Medical Care (2005) and several court rulings on patient rights.

Right to informed consent: The German Constitution, Art. 2 already state that everybody has the right to life and to physical integrity. The freedom of the person is inviolable. In order to perform a medical treatment the consent of the patient is needed first.

Right to information concerning own health: This right is combined with the right to informed consent as it also states that the patient should be fully informed prior to the medical treatment.

Right regarding the medical records: The patient has the right to access his/her medical record.

Right to privacy: Confidentiality between patient and doctor has been laid down in the German Criminal Code Art. 203. It states that it is a crime if a health professional reveals information without authorisation from the patient.

Right to complain and compensation: Complaints can be filed with the direct healthcare provider, furthermore patients' complaints committees are available for complaints, mostly already accommodated by the hospitals.

Greece

In 1992 the Act on Modernisation and Organisation of the Health System (No. 2071/92), Article 47) extended the rights of patients.²² The most important change for patients' right was created in 2005 when the new Code of Ethics was made. This new Code (No. 3418/2005) replaces the old Code of 1939 (Code of Regulation of Medical Deontology of 1955). The Code of Practice of Medicine of 1939 remains valid.²³

²² Leino-Kilpi, H. (2000). *Patient's Autonomy, Privacy and Informed Consent*. Amsterdam.

²³ Goffin, T. et al., "Patient Rights in the EU - Greece", *European Ethical-Legal Papers N°6*, Leuven, 2007.

Right to informed consent: Consent must be given by the patient. If a patient is not competent, consent for a medical treatment should be given by the legal representative of the patient. This is stated by Greek Constitution in Art. 47 (3) and Art 12 of the Code of Ethics 2005.

Right to information concerning own health: A healthcare worker or physician is obligated to fully inform the patient. This is stated in Art 11 of the Code of Ethics 2005. The information should include the content, risks and possible outcomes of the treatment. The therapeutic exception should be applied only in specific circumstances and the physician has to prove that the withholding of information from the patient is justified for therapeutic purposes.

Right regarding the medical records: This aspect is embedded within the same articles as the right to information.

Right to privacy: The physician has the obligation to keep the medical information confidential. This obligation is absolute as the physician has to keep the necessary discretion regarding third parties that take part in the medical service.

Right to complain and compensation: Every patient has the right to submit complaints and objections. Furthermore the office of Ombudsman is created especially for complaints relating to healthcare and welfare. Civil liability of a physician arises when provisions of civil law are violated by act or by omission. The Act 2251/94 on Consumer Protection provides in Art. 8 rules concerning the liability of the service supplier.

Hungary

General rights of patients are stated in Chapter II (Rights and obligation of patients) and Chapter VI (Rights and obligation of healthcare workers) of the Health Act CLIV of 1997.²⁴

Right to informed consent: The right of self-determination is guaranteed in Section 5 of the Health Act. The patient has the right to be involved in the decisions concerning examination and treatment. The patient's informed consent is a precondition of all medical interventions, unless otherwise provided for in the Health Act.

Right to information concerning own health: This right is covered in Section 13. The patient has a right to receive the information in an individualised form. Furthermore the legal regulation of the therapeutic exception is not provided as such. However, the physician has still the option to inform the patient gradually when necessary, considering the patient's condition and circumstances. Both the right of informed consent and information are more specified in Section 16.

Right regarding the medical records: This right is implied by the Health Act in Section 24. The patient has the right to access his/her medical file.

Right to privacy: The Health Act provides a right to privacy for the patient in both Section 24 and Section 25. A patient has the right to have his/her examination and treatment taken under strict private circumstances. Furthermore, the patient has the right to have only those persons present whose involvement is necessary.

²⁴ Hungary. *Health Act CLIV*. 1997.

Right to complain and compensation: The patient has the right to file a complaint with the healthcare service provider as is provided in Section 29 of the Health Act. In Hungary damage resulting from health services is compensated according to the rules of the Hungarian Civil Code.

Ireland

Ireland's patients' rights legislation is divided in several acts; such as the Health Act 2005, the Mental Health Act 2001 and the Medical Practitioners Act 2007. Also the Charter of Patient's Rights is used.

Right to informed consent: In general, valid consent must be informed consent. The law is not clear on exactly how much information a doctor must give a patient. Consent is now legally defined for the purposes of psychiatric treatment (Mental Health Act 2001) but not for other treatments.

Right to information concerning own health: The Freedom of Information Act, 2003 obliges government departments, the Health Service Executive (HSE), local authorities and a range of other statutory agencies to publish information on their activities and to make personal information available to citizens (including patients).

Right regarding the medical records: A medical record needs to be made and the patient has the right to access it under the Data Protection Act 2003.

Right to privacy: The Charter of Patient's Rights states that the patient has the right to have his/her privacy respected, especially when the nature of the clinical condition is being discussed with hospital staff. Furthermore the patient has the right to total confidentiality in respect to the medical records.

Right to complain and compensation: There are various options for complaints in Ireland. The patient can file a complaint at one of these institutions (depending on the complaint): the Ombudsman; the Medical Council; or the Nursing Board.

Italy

In Italy the rights of patients are regulated by the Code on Medical Ethics. However, this Code is not legally binding. Although there is no concrete and separate patients' rights legislation in Italy patients still enjoy certain rights.²⁵

Right to informed consent: The Italian Constitution guarantees the inviolability of personal liberty. In particular, consent to medical treatment is covered by Article 32 (2) of the Constitution. This article states that nobody may be forced to undergo any particular medical treatment, unless under the provision of the law.

²⁵ Katholieke Universiteit Leuven.. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Italy. (2008).

Right to information concerning own health: The right of the patient to information about his/her health is not stipulated as a specific right. The Code of Medical Ethics deals with the obligation of granting information in the context of the right to informed consent.

Right regarding the medical records: This right is not provided by the Code of Medical Ethics. This right may be deducted from section 92 of Article 96/2003 on data protection. But this mainly deals with the protection of the data and not with the above-mentioned rights.

Right to privacy: The profession secrecy is penalised by Art. 622 of the Italian Criminal Code. Additionally the Code of Medical Ethics also enforces the professional confidentiality. The physician should maintain secrecy about everything that is entrusted to him/her and about what he/she can get to know due to his/her profession.

Right to complain and compensation: In case of routine operation, medical professionals are subject to strict liability. In case of complex operations the courts call for a high level of professional care and attentiveness.

Latvia

The patients' rights legislation in Latvia does not yet cover all patients' rights. The Latvian Constitution declares in article 11 that the State shall protect human health and guarantee a basic level of medical assistance for everyone. Furthermore a Law on Medical Care and a Law on Pharmaceuticals are in force. The only regulations concerning specific patients' right can be found in a chapter of the Medical Treatment Law.²⁶

Right to informed consent: A physician must receive consent from the patient before the treatment.

Right to information concerning own health: A patient shall have the right to receive information in an understandable way from the healthcare provider concerning his/her health. The therapeutic exception may be applied by the physician.

Right regarding the medical records: The practising physician keeps medical records in accordance with the procedures of the Minister of Welfare on grounds of Art. 59 of the Medical Treatment Act. The patient has the right to obtain all information from his/her medical record.

Right to privacy: Information regarding the medical treatment of a patient, the diagnosis and prognosis of a disease, as well as all information obtained during the procedure shall be confidential.

Right to complain and compensation: The main institution that registers and deals with complaints is the State Health Inspectorate under the Ministry of Health. Through the 1997 "Law on Medical Care" there is the possibility to penalize health providers, or transfer complaints to the state prosecutor's office. There is however no specific compensation system in place in Latvia. A few court proceedings with verdicts demanding payment for patients

²⁶ Katholieke Universiteit Leuven. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Latvia. (2008).

created discussions about liability insurance for providers. However up till now these discussion have not been transferred to the legal system.

Lithuania

The rights of patients are regulated by the Constitution of the Republic of Lithuania, the Civil Code (2000), and the Law on the Rights of Patients and Compensation of the Damage to their Health (1996).²⁷ The new Civil Code of Lithuania was adopted in 2000, came into effect as of 1 July 2001 and was last amended in 2009.²⁸

Right to informed consent: This right is formulated in both the Law on Patients' Rights and the Civil Code. The Law on Patients' Rights provides that a patient may not be treated against his/her will. Informed consent is thus needed to start the medical treatment.

Right to information concerning own health: This right is regulated as a basic requirement in the Law on the Rights of Patients and Civil Code. This latter also covers the therapeutic exception.

Right regarding the medical records: The right of the patient to a medical record is formulated in terms of an obligation for the healthcare providers both in the Civil Code and in the Law on the Rights of Patients. The Lithuanian law states that the patient does not require any involvement of any healthcare provider to get access to medical records. The patient thus has the right to directly access his/her records.

Right to privacy: Although the law provides for the right to protection of confidential information, in practice there are too few concrete guidelines of this legislation.

Right to complain and compensation: The Law on the Rights of Patients contains rules regarding the right to complain. The same Law also contains very specific rules with regard to the compensation of damage caused by the provision of healthcare.

Luxembourg

Luxembourg does not have a specific patients' rights' Act. Instead Luxembourg uses two main documents in providing the rights of patients. The Act on hospital establishments of 28 August 1998 contains in Chapter 10 a catalogue of important patients' rights.²⁹ These rights are however mostly focussed on patients that are admitted in a hospital. However, a new Code of medical ethics also has been adopted and is legally binding. Chapter IV of this Code contains information about the relations between the doctor and the patient.³⁰

²⁷ Lithuania. Law (Text No. I-1562) of the Republic of Lithuania of 3 October 1996 on the rights of patients and compensation of the damage to their health.

²⁸ Civil Code of the Republic of Lithuania. 18 July 2000. (last amended on 21 July 2009).

²⁹ Luxembourg. Law of 28 August 1998 on hospital establishments. (*Mémorial : Journal Officiel du Grand-Duché de Luxembourg, Part A, 18 September 1998, No. 78, pp. 1564-1672*).

³⁰ Luxembourg. Ministerial Order of 7 July 2005 approving the Code of Ethics of the professions of physician and dentist, issued by the Medical College. (*Mémorial : Journal Officiel du Grand-Duché de Luxembourg, Part A, 27 September 2005, No. 160, pp. 2752-2769*)

Right to informed consent: The Act on Hospital Establishments (Art. 40, paragraph 1) stipulates that a patient, when he/she is incorporated in a hospital and during his/her further stay, has the right to sufficient information concerning his/her health condition and concerning the treatment proposed and this with a view to giving informed consent. This information must be supplied by the physician (Art.40, paragraph 2).

Right to information concerning own health: The Act on Hospital Establishments mentions the right to information on the health of the patient, but this is only in relation to the information preceding the consent.

Right regarding the medical records: The same Act contains some provisions concerning the medical record. The patient has the right to access his/her individual record.

Right to privacy: Always according to this Act (Art. 38) every patient is entitled to confidentiality and privacy.

Right to complain and compensation: Every hospital director has the obligation to create a mechanism through which complaints can be treated.

Malta

Malta primary patients' rights' sources are the Patients' Rights' Charter (1998); the Patients' Charter National Hospital (2002); the Data Protection Act (2001) and the Criminal Code (Art. 257).

Right to informed consent: The Patients' Rights' Charter states that a patient may give or withhold his/her consent to medical treatment. The Patients' Charter National Hospital also refers to this in the context of hospitals.

Right to information concerning own health: There is no separate legislation on this issue, as this is combined with the right to informed consent where information needs to be given before the beginning of the treatment.

Right regarding the medical records: Medical records are primarily kept so that a patient's condition can be documented and care planned accordingly. There are no statutory guidelines as to the type or extent of information, which a physician is deemed to keep about the patients under his/her care. This is left to the physician's discretion.

Right to privacy: Art. 257 of the Criminal Code safeguards the confidentiality between the physician and patient. Furthermore the Data protection Act enforces the right to privacy regarding the protection of personal data.

Right to complain and compensation: In the public sector a patient lodges a complaint with the Customer Care of the Health Department. In the Private sector it is the Medical Council of Malta which deals with such issues.

The Netherlands

The rights of patients have a solid place in the Dutch legal system as several rights are placed in the Act on the medical treatment contract of 1 April 1995.³¹ The Act is a part of the Dutch civil code. The main purpose of the Act is to clarify and strengthen the legal position of the patient. However, recently the Dutch government has provided the main patients' rights in one document. This document should go into force in 2010, therefore the document has not yet been included in this overview of patients' rights.

Right to informed consent: Informed consent has two components: information and consent. This right to information stems from the patient's right of self-determination as laid down in articles 10 and 11 of the Dutch Constitution. This means that the medical treatment of patients is only allowed with their consent or that of people empowered to decide for them. Consent to treatment is a basic principle in healthcare and serves as the justification of the doctor(s) intervention.

Right to information concerning own health: This right has been incorporated with the right to informed consent.

Right regarding the medical records: The healthcare provider shall keep a record relating to the treatment of the patient. He/she shall use the file to record data concerning the health of the patient and the procedures performed on the latter.

Right to privacy: The Dutch Constitution states that everyone shall have the right to respect for his/her privacy. Although the right to medical secrecy and the protection of the medical data are regulated, no specific regulations on the right to privacy for patients are stipulated in the Dutch Medical Law.

Right to complain and compensation: When a patient is not satisfied with the treatment provided, he/she has several options. He/she can file a direct complaint to the healthcare provider or to the complaint committee of the healthcare institute itself. The patient can try to file for compensation when a medical error has been made. However these procedures are very hard as it is the patient who needs to prove that a medical error has been made.

Poland

Patients' rights are regulated in many different legal acts. The most important one is the Act of 30 August 1991 on Healthcare Institutions as this Act was the first one to specify the fundamental rights of patients.³² The general right to healthcare and additional healthcare rights of every Polish citizen are granted in the Polish Constitution (Art.68).³³

Right to informed consent: The Act on Healthcare Institutions affirms and combines the right to informed consent and the right to patient information. The patient has the right to express his/her

³¹ Wet van 17 november 1994, houdende bepalingen omtrent de overeenkomst tot het verrichten van handelingen op het gebied van de geneeskunst, *Wet geneeskundige behandelingsovereenkomst*, Stb. 1994, 837.

³² European Observatory on Health Care Systems. *Healthcare Systems in Transition, Poland*. 1999.

³³ The Constitution of the Republic of Poland. As adopted by the National Assembly on 2nd April 1997.

consent to accept health services or to refuse them after receiving the sufficient amount of information.

Right to information concerning own health: This right is thus embedded with the rights of informed consent within the Act on Healthcare Institutions.

Right regarding the medical records: Medical institutions have the obligation to maintain an individual health record. The patient has the right to access this file.

Right to privacy: The Polish Constitution (Art. 41 and 49) states the right to protect private life and the protection of privacy.

Right to complain and compensation: The main institution regarding the right to complain is the Ombudsman. In the case when a patient's rights are infringed, the court may require the physician (hospital) to pay pecuniary compensation to the injured person for the harm caused.

Portugal

Some provisions related to patients' rights are laid down in the Basic Law on Health 48/90 of 24 August 1990. However, more legislation has been made after this and includes the Mental Health Act 36/98, the Law 12/2005 on Health Information, the Law 60/2003 on Primary Healthcare and the Law 281/2003 on Continuous Healthcare. Each of them includes several issues related to patients' rights.³⁴

Right to informed consent: Patients have the right to decide to accept or to refuse healthcare. They have also the right to be informed about their situation, the possible alternatives of treatment and the probable evolution of their condition.

Right to information concerning own health: Portugal also has clustered this right within the right to informed consent. However, the therapeutic exception should be interpreted in a very restrictive way. It may only be used if disclosure of information would aggravate cardiac or psychic illnesses.

Right regarding the medical records: The medical information must be kept in the medical records by the physician who treats the patient. The Portuguese Constitution stipulates that all citizens have the right to access the data related to them.

Right to privacy: Law 12/2005 on Health Information states that the persons responsible for the processing of health information are responsible to protect confidentiality.

Right to complain and compensation: No special legal provisions have been found regarding the right to complain.

³⁴ Katholieke Universiteit Leuven. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Portugal. (2008).

Romania

Romanian patients' rights are primarily combined and defined within the Patient's Rights' Act of 2003. Other legislations that cover patients' rights are the Romanian Constitution (1991); the Health Reform Law (2005); the Mental Health Law (2002); the Public Health Law (1998) and the Deontological Code of Medical Profession.

Right to informed consent: The patient has to give his/her informed consent before the treatment may be started. An arrogation of decision can go to a committee of arbitration.

Right to information concerning own health: The patient has the right to be informed completely and in an accessible manner as laid down in the Patient's Rights' Act.

Right regarding the medical records: A medical record needs to be updated; furthermore the patient has the right to access this record.

Right to privacy: The patient has the right to privacy and confidentiality. Also the data from the medical records need to be kept secret. There can be no disclosure without the authorisation of the patient. The right to privacy is basically laid down in the Romanian Constitution.

Right to complain and compensation: According to the Patient's Rights' Act, the patient has the right to complain and appeal.

Slovakia

Slovakia has a broad legal framework concerning patients' rights. The Slovak Constitution, the healthcare reform package of six Acts of 2004 and especially Act No. 576/2004 on healthcare and healthcare-related services are the main legal documents.³⁵

Right to informed consent: The right of a patient to informed consent is one of the basic patients' rights in Slovakia. The informed consent shall be given by the patient or by his/her legal representative if he/she is incapable to give informed consent.

Right to information concerning own health: Art 11 of Act No 576/2004 covers this right as a separate right. It stipulates that each person has the right to be informed about his/her health condition.

Right regarding the medical records: Art. 18 and 19 of Act No 576/2004 are devoted to this right and give the definition of a medical record. The maintaining of a medical record is an obligation for the healthcare provider.

Right to privacy: All healthcare providers are obligated to uphold confidentiality. The Act on Healthcare assures the right to professional secrecy as a patient's right.

³⁵ The National Council of the Slovak Republic. Act. No. 576/2004 Coll. On Healthcare and Healthcare-related Services. (2004).

Right to complain and compensation: This right is well known and much used in Slovakia. The patient has several options to file a complaint. Most of them are filed with the Healthcare Surveillance Authority. Concerning infringement of the patients' rights Act No 576/2004 makes a reference in Art. 11. A patient that feels that his/her rights have been violated is obligated to seek court protection. The general provisions with regard to civil liability of the Act 40/1964 of the Civil Code will apply.

Slovenia

The Act on Patients' Rights is the main Act concerning patients' rights in Slovenia. Its main goal is to enable equal, solid and safe healthcare. Also the Health Service Act still includes several patients' rights.³⁶

Right to informed consent: This right is based in the Slovenian Constitution that determines the right to personal dignity. The main principle is that the patient's consent is needed for any medical procedure.

Right to information concerning own health: Under Article 20 of the Patients' Rights' Act, the patient has the right to be informed about all aspects concerning his/her state of health. The therapeutic exception is set down in Article 22, section 1 of the Act on Patients Rights.

Right regarding the medical records: Although the Slovenian legislation does not specifically state any rules on medical records, the Patients' Rights' Act already indirectly indicates, in the section concerning the right to information, that the patient has a right to get information from his/her medical file.

Right to privacy: The patient has a right to have his/her personal data kept confidential. This includes all data considering visits, treatments and other information related to medical care. The right to privacy is stated within the Slovenian Constitution.

Right to complain and compensation: The Patients' Rights' Act covers the breaching or violation of the patients' rights. The Act lays down the procedure and the institutions where the patient can file his/her complaint. Also the Ombudsman is involved in especially monitoring patients' rights. Civil Law is used for the liability of damages against patients.

Spain

Spain primary uses two Laws concerning patients' rights; the General Law on Public Health (1986)³⁷ and the Law on Autonomy of the Patient and the Rights and Obligations with regard to Information and Clinical Documentation (2003).

Right to informed consent: The Patients' Rights Law covers the topic of informed consent. It states that after receiving proper information, the patient can decide what action concerning his/her health can be undertaken.

³⁶ Katholieke Universiteit Leuven. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Slovenia. (2008).

³⁷ European Observatory on Health Care Systems. *Healthcare Systems in Transition, Spain*. 2000.

Right to information concerning own health: This right has been separated from the right to informed consent. Patients have the right to receive any information available concerning their health unless otherwise provided for by law. The therapeutic exception is also provided within the Patients' Rights' Law.

Right regarding the medical records: It is an obligation that all patients who are using healthcare have a record of their medical data.

Right to privacy: The obligation for the right of privacy can be found both in the Spanish Criminal Code and in the Patients' Rights Law. All patients have the right for confidentiality regarding their medical and health data.

Right to complain and compensation: The right to complain is not covered by the Patients' Rights' Law. The General Health Law deals with this issue and states that any patient has the right to file a complaint. The right for compensation is not covered in the healthcare legislation. The General Consumers Protection Act needs to be applied in this case.

Sweden

Patients' rights in Sweden are covered by several different acts. The Health and Medical Personal Duties Act, as well as the Code on Parents, Guardians and Children are a few examples. Patients' rights are laid down in a Charter by the Federation of County Councils. This Charter can not be used in courts as it is not legally binding.³⁸

Right to informed consent: All medical treatments demand the consent of the patient.

Right to information concerning own health: The Health and Medical Services Act states that patients must be informed of their state of health and of the treatment methods available within the county council area.

Right regarding the medical records: The patient has a right to his/her own medical journal. The Patient Journal Act states that the patient also has the right to obtain a copy of this journal.

Right to privacy: Several Acts and Laws provide the right of privacy in Sweden. Among them are the Health and Medical Services Act, the Secrecy Act and the Care registrations Act. Both medical secrecy and privacy issues are tackled within these documents.

Right to complain and compensation: Every county council must have a local advisory committee where patients can file in complaints. The Patient insurance Act contains provisions about the right of patients' compensation when suffering an injury. Also the Tort Liability Act covers this section.

³⁸ Katholieke Universiteit Leuven. European Centre for Biomedical Ethics and Law. Patients' Rights Legislation in Sweden. (2008).

United Kingdom

There is no general patient's rights legislation in the UK. Human rights acts have created a situation in which patients can apply these rights in the context of patients' rights. Besides the case laws, the Patients' Charter also gives some direction of patients' rights in the UK.

Right to informed consent: According to several guidelines of the General Medical Council the physician should ask for the patient consent before starting a treatment. Also the patient should receive adequate information about the treatment.

Right to information concerning own health: This right is thus intertwined with the right to informed consent. The therapeutic exception is allowed in specific circumstances.

Right regarding the medical records: This right has been laid down in the Data Protection Act of 1998. Patients have the right to access their medical record at all times.

Right to privacy: The Common Law covers the relationship regarding doctors and patients and the need for confidentiality. The doctors are obligated to respect the confidentiality of the patients. The Common Law however does not cover the right on privacy, which is protected by the Data Protection Act.

Right to complain and compensation: Complaints can be filed within the National Health Service; if this does not lead to a satisfying reply the Ombudsman can also be advised.

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