



# **SMART 2007/0059**

Study on Legal Framework of Interoperable eHealth in Europe

# **NATIONAL PROFILE HUNGARY**

European Commission
Directorate General Information Society

Brussels

Document ref.: ............INFSO\_eHealth\_Legal/HU-Profile



# Study on Legal Framework of Interoperable eHealth in Europe

Table of Contents	
SMART 2007/0059	1
EUROPEAN COMMISSION	1
1 DOCUMENTS	4
1.1 APPLICABLE DOCUMENTS	4
1.2 REFERENCE DOCUMENTS	4
2 GLOSSARY	6
2.1 DEFINITIONS	6
2.2 ACRONYMS	7
3 INTRODUCTION	9
3.1 GENERAL OVERVIEW OF THE HUNGARIAN HEALTHCARE SYSTEM	9
3.2 Use of ICT in the Hungarian healthcare sector	12
3.3 National eHealth strategy	13
3.4 REGULATORY FRAMEWORK FOR PATIENTS' SUMMARIES	16
3.5 REGULATORY FRAMEWORK FOR TELEMEDICINE	16
3.6 REGULATORY FRAMEWORK FOR ELECTRONIC PRESCRIPTIONS	17
3.7 OVERVIEW OF RELEVANT LEGISLATION	17
4 REGULATORY FRAMEWORK FOR THE HEALTHCARE PROFE	SSION 19
4.1 LEGAL CONDITIONS FOR THE PRACTICE OF HEALTHCARE	20
4.2 CONTROL OVER THE PRACTICE OF MEDICINE	22
4.3 PROFESSIONAL LIABILITY	23
4.4 Professional secrecy	23
5 PROCESSING OF PERSONAL HEALTH DATA	24
5.1 SHORT OVERVIEW OF PERSONAL DATA PROTECTION LEGAL FRAMEWO	ORK 24
5.2 Transposition of article 8 of Directive 95/46/EC	24
5.3 INFORMATION AND ACCESS RIGHTS OF DATA SUBJECTS	25
5.4 OTHER RELEVANT RULES REGARDING PERSONAL DATA PROTECTION	25
6 RIGHTS AND DUTIES OF HEALTHCARE PROVIDERS AND PA	TIENTS 27
6.1 SCOPE OF THE LAW	27

Issued on: ..... 30/09/2008



# Study on Legal Framework of Interoperable eHealth in Europe

6.2	DUTY OF THE PATIENT TO CO-OPERATE	27
6.3	RIGHT TO QUALITY CARE	28
6.4	RIGHT TO FREE CHOICE	28
6.5	RIGHTS RELATED TO INFORMATION ABOUT THE STATE OF HEALTH	28
6.6	RIGHT TO GIVE CONSENT	28
6.7	RIGHTS RELATED TO THE PATIENT'S MEDICAL RECORD	28
6.8	RIGHT TO PROTECTION OF PRIVACY AND INTIMACY	28
6.9	RIGHT TO REPRESENTATION IN CASE OF INCOMPETENCE	29
<u>7                                    </u>	IDENTITY MANAGEMENT IN THE HEALTH SECTOR	30
7.1	Overview	30
7.2	THE SIS CARD	31
7.3	PATIENT IDENTIFIER	32
7.4	AUTHENTICATION OF HEALTHCARE PROFESSIONALS	32
7.5	EXCHANGE OF HEALTH-RELATED DATA	33
<u>8</u> <u>I</u>	ELECTRONIC PRESCRIPTION	34
9 (	GENERAL ASSESSMENT	35
<u>ANN</u>	NEX: CONTACT DETAILS OF NATIONAL CORRESPONDENTS	36
9.1	PRIMARY CONTACT	36
9.2	ALTERNATIVE CONTACT	36

Issued on: ...... 30/09/2008





# 1 Documents

# 1.1 Applicable Documents

[AD1]	Services Contract 30-CE-0162056/00-04

### 1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 <a href="http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356">http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356</a> <a href="http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356">http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356</a> <a href="http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356">http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356</a> <a href="https://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356">https://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356</a> <a activities="" docs="" ec.europa.eu="" ehealth-ap-prog-report2005.pdf"="" health="" href="https://ec.europa.eu/information_society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/com_andreaded-action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/action-society/doc/qualif/health/actio&lt;/th&gt;&lt;/tr&gt;&lt;tr&gt;&lt;td&gt;[RD2]&lt;/td&gt;&lt;td&gt;eHealth Action Plan, Progress Report &lt;a href=" http:="" information_society="" policy="">http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf</a>
[RD3]	Recommendation of the Commission on eHealth interoperability, <a href="http://ec.europa.eu/information_society/activities/health/docs/policy/200807">http://ec.europa.eu/information_society/activities/health/docs/policy/200807</a> <a href="https://ec.europa.eu/information_society/activities/health/docs/policy/200807">https://ec.eu/information_society/activities/health/docs/policy/200807</a> <a href="https://ec.europa.eu/information_society/activities/health/docs/policy/200807">https://ec.eu/information_society/activities/health/docs/policy/200807</a> <a database="" database.html"="" href="https://ec.europa.eu/information_society/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/health/docs/policy/activities/h&lt;/td&gt;&lt;/tr&gt;&lt;tr&gt;&lt;td&gt;[RD4]&lt;/td&gt;&lt;td&gt;Database of European eHealth priorities and strategies (Empirica), &lt;a href=" http:="" www.ehealth-era.org="">http://www.ehealth-era.org/database/database.html</a> (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, <a href="http://www.euro.who.int/observatory/Hits/TopPage">http://www.euro.who.int/observatory/Hits/TopPage</a>
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, <a href="http://www.euro.who.int/observatory/Publications/20060522_4">http://www.euro.who.int/observatory/Publications/20060522_4</a>
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, <a href="http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf">http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf</a>
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: <a href="http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf">http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_report.pdf</a> ,

Document ref.: ...... INFSO\_eHealth\_Legal/HU-Profile



# Study on Legal Framework of Interoperable eHealth in Europe

	Country profiles:
	http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index
	en.htm
[RD9]	Communication from the European Commission, "A Community
	framework on the application of patients' rights in cross-border healthcare",
	2 July, 2008, <a href="http://ec.europa.eu/health-eu/doc/com2008415_en.pdf">http://ec.europa.eu/health-eu/doc/com2008415_en.pdf</a>
[RD10]	Proposal for a Directive of the European Parliament and of the Council on
	the application of patients' rights in cross-border healthcare,
	http://ec.europa.eu/health-eu/doc/com2008414 en.pdf
[RD11]	European Commission, IDABC, eID interoperability for public government
[וועאן	
	services (with country profiles):
	http://ec.europa.eu/idabc/en/document/6484/5938
[RD12]	European Commission, IDABC, eSig-Web (Electronic signatures
	applications in public government services – country overviews):
	http://ec.europa.eu/idabc/en/chapter/6000
	http://oc.ouropu.ou/ouron/onapton/ouou
[RD13]	Legally eHealth, Study on Legal and Regulatory Aspects of
	eHealth,http://www.ehma.org/projects/default.asp?NCID=140
	Circardi, http://www.cima.org/projects/default.asp!14CiD=140
[RD14]	Directive 95/46/EC of the European Parliament and of the Council of 24
[KD14]	
	October 1995 on the protection of individuals with regard to the processing
	of personal data and on the free movement of such data,





# 2 Glossary

#### 2.1 Definitions

In the course of this Study, a number of key notions are frequently referred to. To avoid any ambiguity, the following definitions apply to these notions and should also be used by the correspondents.

- Authorization: refers to:
  - o the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
  - o or: the process of determining, by evaluation of applicable permissions, whether an authenticated entity is allowed to perform a defined action or has access to a defined resource.
- **Data authentication**: information provided for verification, with more or lesser degrees of certainty, of the origin and the integrity of data.
- **eHealth**: a very broad term that encompasses many different activities related to the use of the information and communication technology (ICT) for healthcare. Many of these activities focus on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care.
- **Electronic health record**: a comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes;
- **Electronic signature**: data in electronic form which are attached or logically associated with other electronic data and which serve as a method of data authentication.
- **ePrescription**: a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC47, issued and transmitted electronically
- **Healthcare**: the prevention, treatment, and management of illness and the preservation of mental and physical well being through the services offered by the medical, nursing, and allied health professions. Health care embraces all the goods and services designed for people's health, including preventive, curative and palliative interventions, whether directed to individuals or to populations.
- **Health professional**: a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



### Study on Legal Framework of Interoperable eHealth in Europe

activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

- **Identification**: using claimed or observed attributes of an entity (e.g. a person) to distinguish the entity in a given context from other entities it interacts with (= entity authentication).
- **Identifier**: attribute or set of attributes of an entity (e.g. a person) which uniquely identifies the entity in a given context.
- **Identity management**: Identity management (ID management) is a broad administrative area that deals with identifying entities in a system (such as a country, a network, or an enterprise) and controlling their access to resources within that system by associating user rights and restrictions with the established identity.
- **Patient**: any natural person who receives or wishes to receive health care in a Member State;
- **Patient summary**: subsets of electronic health records that contain information for a particular application and particular purpose of use, such as an unscheduled care event or ePrescription;.
- **Registration**: process in which a partial identity is assigned to an entity and the entity is granted a means by which it can be authenticated in the future.
- **Telemedicine**: exchange of medical information from one site to another via electronic communications with the purpose to improve patients' health status.

#### 2.2 Acronyms

CBSS	Crossroads Bank for Social Security
EHR	Electronic Health Record
eID	Electronic Identity
eIDM	Electronic Identity Management
GP	General Practitioner
HiT	Health in Transition

Document ref.: ...... INFSO\_eHealth\_Legal/HU-Profile



# Study on Legal Framework of Interoperable eHealth in Europe

OCSP	Online Certificate Status Protocol
PKI	Public Key Infrastructure
••••	
NRN	National Register Number
••	
SIS	Social (security) Information System
•	
SSCD	Secure Signature Creation Device
SSIN	Social Security Identification Number
••••	
TAJ	Hungarian Social Security Identification Number
•••••	
TTP	Trusted Third Party

Page: 8 of 36





### 3 Introduction

### 3.1 General overview of the Hungarian healthcare system

The structure of the Hungarian healthcare system consists in general practitioners (family doctors), dentists, nurses of the mother and child care on the primary level, with primary care duty services. The inpatient and outpatient specialist care, special nurse care are organised by territorial methods. There are outpatient polyclinics for secondary care. The patient should have a referral from the family doctor in most of the cases. The second and third level healthcare served by territorial and "high priority" hospitals. The number of hospitals is higher then the EU average, but there are large regional differences. Ambulance services and blood supply are organised on national level. Pharmaceuticals are distributed through the privat and hospital pharmacies. Healthcare services are provided on the basis of a unique health insurance personal identification number (*TAJ*) as far as the health insurance is compulsory. Nowadays all health service provider and pharmacy shall control in an on-line database the eligibility of the free provision, but the not insured (i.e. not paying the monthly contribution) patient should get the same provision as well.

A comprehensive but not up-to-date overview of the Hungarian healthcare system can be found in the Hungarian HiT country report published by the European Observatory on Health Systems and Policies (written by Peter Gaál <a href="http://www.euro.who.int/Document/E84926.pdf">http://www.euro.who.int/Document/E84926.pdf</a> (WHO, 2004. 162 pp.). There is a more recent and shorter summary of the Hungarian healthcare system form the same author:

http://www.ehma.org/\_fileupload/File/Projects/Benefit\_Report\_Hungary.pdf, and some other documents about the freshest reform of the Hungarian healthcare system (e.g. The 2007-2009 Reform of Hungarian Health Insurance System http://www.eum.hu/download.php?docID=1318)

From these documents, we reproduce the following important observations:

"By the end of the 1980's, Hungary witnessed the beginning of a large scale healthcare reform. The so-called state-socialist, Semashko system was characterized by the overwhelming dominance of the state in both the financing and the delivery of services. The uniform model of the highly centralized, integrated health services was abolished. Replacing the tax based financing of the state-socialist system, as one of the first countries in the Central and Eastern European region, Hungary reverted the earlier Bismarckian model of compulsory social insurance in 1990, established the Health Insurance Fund (HIF) in 1992 and its national administration (hereafter NHIFA or OEP) in 1993." In realty the model is a Bismarck-Beveridge mix, because less then 40 % of the population pay the fees.

"The lack of consensus about decentralization in recent Hungarian healthcare policy is reflected by the pilot status and repeated redrafting of regionalization programmes. Although the legal background of the three privatization options – ownership privatization, functional privatization and corporation – was created in the early 1990s, significant privatization has taken place in primary care only, including the functional privatization of family doctor services and the real ownership privatization of pharmacies. A few hospitals have been given back to their original church owners and are run on a non-profit basis, but the majority of

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



### Study on Legal Framework of Interoperable eHealth in Europe

providers of specialist health services remained in local government ownership. All providers have a contract with the NHIFA for financing the services."

The Constitution assigns overall responsibility for state social welfare and healthcare provisions to the national government. *Act CLIV of 1997 on Health* assigns responsibility for health services to the National Assembly, the national government, the Ministry of Health, the National Public Health and Medical Officer Service (hereafter NPHMOS), and in general the owners of health facilities.

"The 1990 Local Government Act assigned responsibility for local health services to local governments, implying that they should plan health services for the local needs. Responsibility for primary care rests with municipalities and that for secondary care with counties, but they are allowed to contract out service delivery to private providers. There is a large proportion of primary care contracted out to entrepreneur family doctors (under the scheme of the so-called functional privatization), and a smaller segment of secondary care contracted out mainly to a few church-owned hospitals.

Primary care providers (family doctors) are privatized and paid by capitation, outpatient specialist services are paid by fee-for-service (German-type point system), and from the 1<sup>st</sup> of July 1993 hospitals are paid for acute inpatient services on the basis of the Hungarian adaptation of the Diagnosis Related Groups (DRGs). From 2007 there is strict volume-limit on outpatient and acute inpatient performance. Chronic care and some expensive tertiary care services are reimbursed differently, on a per diem basis and a fee per case, respectively. The vast majority of medical doctors and the health workers remained salaried public employees, with the exception of primary care. The minimum salary is determined on a pay scale according to qualifications and years of work experience, but the average salary in the health sector remained among the lowest compared to other sectors of the economy."

Act CXXXII of 2006 aimed the restructuring of the hospital network of almost 200 independent units, introduced a four level system of the health services from January 2007:

- High priority hospitals (reachable in 55 kms in average)
- Territorial hospitals (reachable in 30 kms in average)
- Outpatient centres (reachable in 20 kms in average)
- Family doctors

Another important change is the limitation of free hospital choice through the modification of the referral system. Insured patients without referral have to pay a co-payment of 30 per cent but maximum HUF 100 000 ( $\approx$  € 400) of the full costs of treatment. The family doctor's freedom is going to be limited to three local hospitals. The act introduced co-payments from 15 February 2007 in the amount of HUF 300 per visit, or per hospital day. Though the fee is symbolic ( $\approx$  € 1.2), and there were many exceptions (e.g. children under 18), a referendum was initiated and the co-payment was cancelled since April 2008, however.

The act about the re-regulation of the drug market made a counter-incentive scheme for physicians, family doctors in particular, against the prescription of expensive medicaments. New measures are introduced to support generics. Free, downloadable software will help doctors in this. Prescriptions will be verified in each and every Hungarian pharmacy via online connection to a central data base.

Document ref.: ...... INFSO\_eHealth\_Legal/HU-Profile



#### Study on Legal Framework of Interoperable eHealth in Europe

There will be no free prescription drugs anymore: patients will have to pay a minimum HUF 300/box, even if the drug is 100% subsidized. The market of pharmacies will be liberated in two important ways. First, the existing protective rules which prevent the opening of new retail outlets are abolished, if the pharmacy provides extra services (e.g. extended opening hours, permanent duty, etc.). Second, certain non-prescription drugs are allowed to be sold outside of pharmacies. Stores that wish to sell non-prescription drugs must, however, get a certification from the NPHMOS.

"Health services in Hungary are funded primarily by social health insurance from the Health Insurance Fund (HIF) for recurrent costs, administered by the National Health Insurance Fund Administration (NHIFA). Capital costs are mainly financed from taxation. Services are delivered predominantly by local government-owned public providers, who contract with the NHIFA. The national government is the dominant regulator of health services, exercising statutory supervision over the HIF and controls the NHIFA. In addition, it provides capital grants and delivers public health and some tertiary care services."

Act LXXX of 1997 on Those Entitled for the Services of Social Insurance and Private Pensions and on the Funding of these Services sets out the rules of participation in the social health insurance scheme, and the entitlement for in-kind and cash benefits. Membership is compulsory for all citizens living in Hungary (that is, people with the personal identification card); opting out is not permitted. A citizen should pay a monthly contribution. The social health insurance scheme provides nearly universal coverage and a comprehensive benefit package with few exclusions and little or no co-payment except for dental care, pharmaceuticals, medical aids and prostheses and balneotherapy.

The idea of competing health insurance funds and the establishment of multiple health insurance funds, decentralization of the HIF and the NHIFA have long been on the political agenda since 1994. Act I. of 2008 on the Health Insurance Management introduced only the "multiple insurance fund model" accepted by the Parliament in March 2008. "The health insurance reform has been in the crossfire of constant professional and political controversies, and with the support of the opposition, sufficient signatures have been collected for a new referendum aimed to prevent the restructuring of the insurance system. All this put into doubt the implementation of the new health insurance act and also created uncertainty among potential investors." The Act was withdrawn soon.

Residents of the ECC countries, who are entitled to health care of the National Health Service or mandatory health insurance scheme of their respective countries of residence, can receive in Hungary the health care: which becomes necessary on medical grounds, during temporary stay in Hungary taking into account the *nature* of the benefits required and the *expected* length of stay.

The treatment, which becomes medically necessary during the patient's temporary stay in Hungary, is free of charge. In case of doubt the healthcare provider decides whether the needed treatment is medically necessary during the expected duration of the stay in Hungary. However, by virtue of decisions of the European Commission (No 2004/481/EC and 2004/482/EC), all treatments are deemed necessary in case of

- dialysis,
- oxygen therapy and

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile





pregnancy and childbirth.

### 3.2 Use of ICT in the Hungarian healthcare sector

The first national computer centre with the tasks of eHealth development (GYOGYINFOK recently a department of the NHIFA with sectoral responsibility http://www.gyogyinfok.hu/magyar/tortenet.html) was established in 1974. GYOGYINFOK prepared information and expert systems for the healthcare and issuing free software's for the nation wide data processing and data collection of statistical data and of the reimbursement. Due to this the personal computers with modems at least are common at the Hungarian healthcare providers. The data were submitted by floppy discs or on the X.25 network for the NHIFA. Currently instead of mailing the floppies or connecting through PSTN Internet connections are applied, in the case of hospitals with electronic signature. The results of the Human Recourses Development Operative Programme Measure 4.4 (hereafter HEFOP 4.4) ICT infrastructure developments project http://www.hefop.hu/uploaded/pages/44/content/HEFOP en 20060503.pdf p. 80.) for the three most backward regions (IT Development in Health Care in the Regions Lagging Behind) are not yet available. The project was closed in March 2008 and the evaluation began. There were built information exchange model networks between hospitals, health centres and family doctors and intra institutional information systems were developed as well. The use of ICT by general practitioners in Hungary has been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe" (Empirica):

http://ec.europa.eu/information\_society/eeurope/i2010/benchmarking/index\_en.htm From the Hungarian country brief, we take over the following key findings:

"Hungary is a solid average eHealth performer in the EU27. In terms of infrastructure, 100% of the Hungarian GP practices use a computer, which puts the country on a par with Estonia, Finland and Sweden where also a computer availability rate of 100% is reached. However, only 49% of Hungarian GP practices make use of an Internet connection, a result which is below the EU27 average of 69%. Broadband connections have not yet fully arrived in Hungary. Only 36% of the Hungarian GP practices make use this type of internet access". (Due to the compulsory on-line TAJ eligibility checking since 2007 there were dramatic changes in this figures after the data collection of the report)

"Electronic patient data storage is quite common in Hungary. The storage of medical and administrative patient data are the eHealth applications the most frequently used in Hungary. Results in this regard clearly exceed European averages.

At least one type of medical patient data is stored in 99% of GP practices. A computer is available in the consultation room in 83% of the Hungarian GP practices. It is actually used for consultation purposes with the patients in 65% of the practices. This "availability versus use" gap can be found in many European countries, sometimes being as high as 50% absolute. In Hungary, 83% GP practices use a Decision Support System either for diagnosis or prescription purposes (50% on average in the EU27).

In Hungary the electronic exchange of patient data via the Internet or other dedicated networks on the other hand is not yet well established. Only 12% of the GP practices receive

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



Page: 13 of 36

### Study on Legal Framework of Interoperable eHealth in Europe

results from laboratories. In Europe this is most frequently used type data transfer (40%). Even less, that is 2% of the GP practices exchange medical data with other health care providers electronically. EPrescribing is also used by only 1% of the Hungarian GP practices. Only 1% of the Hungarian GPs exchange administrative data with other care providers, as compared to an average rate of 10% in EU27. With a use rate of 5% for the exchange of administrative data with reimbursers, Hungary also scores below the EU average of 15%."

### 3.3 National eHealth strategy

A special website was opened for the eHealth programs in 2004. (<a href="http://e-egeszseg.eum.hu/eum/eegeszseg\_angol.news.page?pid=DA\_62075">http://e-egeszseg.eum.hu/eum/eegeszseg\_angol.news.page?pid=DA\_62075</a>). The website summaries in English the strategy and all relevant projects started in 2003-2006: "Although health informatics in Hungary has long traditions, till 2003 a nation-wide, accepted health IT strategy was not operational. In December 2003 the Hungarian Government accepted the Hungarian Information Society Strategy (HISS), followed by the HISS for Health and Social Affairs in 2004 and the National eHealth Programme in 2004, later was complied with the EC eHealth Action Plan (2004-2100). At that time an eHealth programme management unit was set up under the umbrella of the National Institute for Strategic Health Research (ESKI) (<a href="http://www.eski.hu/eprogram/english/english\_index.htm">http://www.eski.hu/eprogram/english/english\_index.htm</a>).

The timelines of the strategies were modified in line with the revised Convergence Program of Hungary which was accepted by the Financial Ministers of EU in October 2006." More recent information can be found on the portal of the Ministry of Health (<a href="http://www.eum.hu/">http://www.eum.hu/</a>) and on the website of ESKI <a href="http://www.eski.hu/index\_en.html">http://www.eum.hu/</a>) and on the website of ESKI <a href="http://www.eski.hu/index\_en.html">http://www.eum.hu/</a>) and on the website of ESKI <a href="http://www.eski.hu/index\_en.html">http://www.ehealth</a> policy with the data of the year 2006 is published in the January 2007 ERA Report "eHealth strategy and implementation activities in Hungary" <a href="http://www.ehealth-era.org/database/documents/ERA\_Reports/eH-ERA\_Hungary\_report\_January\_2007.pdf">http://www.ehealth-era.org/database/documents/ERA\_Reports/eH-ERA\_Hungary\_report\_January\_2007.pdf</a> and the eHealth/ERA Facts Sheet Hungary of March 2007.

A new eHealth strategy was issued for the Health Sector in March 2008 complied with the i2010 eHealth action plan. The new "eEgeszsegugy 2010" realizes that the former strategy was fulfilled only partly. The IT framework for the reform of the healthcare system emerged, however, the uniform legal framework of the data, information and knowledge management and storage is failed, likewise the process of the European standardization and regulation is not yet finished as well.

#### The main results achieved:

- The on-line eligibility checking system is working, which gives an opportunity, to check the legal insurance relationship since April 2007. (E.g. for citizens <a href="https://ugyfelkapu.oep.hu/oepu/keret.jsp">https://ugyfelkapu.oep.hu/oepu/keret.jsp</a> through the central government's Customer Gateway with account name and password, for the healthcare providers with special software and authentication). The citizen can check all insured medical treatments of her/his full life road in the same system.
- The Internet based Hungarian Health Data warehouse of ESKI is available free (IMEA <a href="http://hawk.eski.hu:8080/IMEA/index.html">http://hawk.eski.hu:8080/IMEA/index.html</a> helping the decision making and research

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile





since 2005. A more advanced system provides statistical information based on individual records of health care episodes (hospital and outpatient cases, special serviceses) are available also at ESKI only in Hungarian language (http://hawk.eski.hu:8080/Tea/)

- The Hungarian Health Care Information Service for Citizens Dr.Info is working as a Web information system and call centre as well. <a href="http://drinfo.eum.hu/drinfo/">http://drinfo.eum.hu/drinfo/</a>.
- The typical indicators of hospitals became accessible for anybody on the Internet <a href="http://drinfo.eum.hu/drinfo/pid/0/article/oid/0/Article.22501">http://drinfo.eum.hu/drinfo/pid/0/article/oid/0/Article.22501</a> detailed on <a href="http://www.ebf.hu/index.php?m=8">http://www.ebf.hu/index.php?m=8</a>.
- The basis of information systems supporting the tracking of patient life road, and the prevention came into existence (on line National Cancer Register <a href="http://www.sztaki.hu/kereses/projektek/projekt\_informaciok/?uid=00001">http://www.sztaki.hu/kereses/projektek/projekt\_informaciok/?uid=00001</a>, National Screening System, etc.)
- A special domestic eHealth ITC supplier circle came into existence in the past years, which is himself seeking for the implementation of the modern technologies. <a href="http://www.ivsz.net/engine.aspx?page=csoportmunka">http://www.ivsz.net/engine.aspx?page=csoportmunka</a> ehealth.
- Many specialists trained on the field of the healthcare ITC are available at the healthcare providers, who obtain serious experiences in the course of the developments of the past years.
- The healthcare systems licenses and know how of the earlier programmes, (e.g. ERDF financed Human Recourses Development Operative Programme HEFOP) are free available for domestic use.
- The Hungarian National Ambulance and Emergency Service (HNAES) begin the modernisation of the nation wide alarm management system. http://www.mentok.hu/page.php?newmenuid=6.

There are 14 main objectives of the "eEgeszsegugy 2010" strategy for 2008 - 2013 with the following tasks
Central tasks

- 1. The creation of a system of centralized, authentic and up-to-date basic registers of a central data centre maintaining the tasks and responsibility of the present data controllers and technical data processors. Compiling the data registered and stored in one more places and the development of the following authentic "master" databases: physician and dentist registers, pharmacists registers, clinical academic specialisation psychologists, academic specialisation employees' registers, medicine data registers, SSIN database, National Transplantation Register, etc)
- 2. The definition of the minimal ITC requirements for the health service providers, support of the application of healthcare software's satisfying CEN-MSZE 13606 standards (HIS, RIS, LIS, PACS, etc. systems).

Document ref.: ....... INFSO\_eHealth\_Legal/HU-Profile Page: 14 of 36





- 3. The development of the standardized and up-to-date data model for the data reporting of reimbursement.
- 4. The quantitative reduction of the sectoral data reports. The overview of data ranges and their usage with the participation of the representatives of the medical profession.
- 5. Extending the statistical reporting system over the full scope of the health service providers. It is necessary to define the fundamental data bases, into which justified to involve that service providers too, which have not contracted with the NHIFA. It is necessary to abolish the reporting obligation of the unnecessary and redundant statistical data at the same time.
- 6. Development of conditions to the obligatory application electronic authentication and electronic signature for the patients', for the doctors' and for the specialist healthcare workers' with the emission of the suitable healthcare card. Establishment of a sectoral certification service provider and card management organization providing the services of electronic signature, time stamping and card management. Connecting the card system to the eligibility checking system.
- 7. Support of the application of healthcare document handling systems
- 8. Promotion of the healthcare employees' informatics training, especially in the field of standardisation, of security and of data protection. The Healthcare Professional Training and Continuing Education Council has to include with a bigger emphasis the healthcare informatics in its professional development programs, primarily in the trainings of type A. Support the institutions' individual initiatives for the organization and transaction of ICT training courses.
- 9. The creation of the legal environment of the required actions for the review of the healthcare application of the data protection act.
- 10. The development of the nation wide interinstitutional ICT infrastructure and the provision of its operation.

## ICT action plans of the healthcare system

- 1. Publishing the minimal ICT system requirements for the healthcare service providers (inpatient and outpatient institutions, family doctors), inclusion of the requirements into the conditions of the support
- 2. Provision of the spreading of eGovernment applications in the health sector, especially at the healthcare authorities.
- 3. The support of the fast spreading of the telemedicine
- 4. The development and provision of on line reporting systems of the healthcare provider institutions and specialists for all data provider and data collector. It is necessary to support the development of the existing software's of the healthcare providers resulting the instantaneous recording and on line submission of reports. On the same time the data collecting institutions should be provided such information systems

Document ref.: ....... INFSO\_eHealth\_Legal/HU-Profile Page: 15 of 36 Version:......v1.1





which are suitable for the electronic production of the necessary domestic and international reports.

- 5. The support of healthcare providers' for the introduction of the Internet advance booking. The family doctor would have an opportunity of Internet advance booking for certain medical attendances in the case of existence of a suitable interinstitutional communication infrastructure.
- 6. The reconstruction and continuous development of the Portal of the Health Sector with insertion of the existing websites, providing the information and administration platform
- 7. In the interest of sectoral research and development activities the support of additional model projects, the practical utilisation of the results of former projects until now, primarily HEFOP 4.4
- 8. It is necessary to regulate the electronic storage, archiving of the healthcare data and its availability in case of suitable authorization.
- 9. It is necessary to favour all those healthcare informatics programs, that aim is the dissemination of the technologies helping in the conduct of life e.g. the eVITA national program.
- 10. The solid health policy being founded on facts may not miss the results of research made on data warehouses, implying sectoral, non personal, time series. It is necessary to pay bigger attention to updating the data warehouse in order for it to be possible to make searching always with the freshest data in the future.
- 11. The continuous development of the international contacts, the recognition of the advanced healthcare ICT systems and adaptation the experiences in the course of the forming of the domestic systems. More active participation in the European Union projects, in developments (e.g. WHO Terminology Collaboration Centre Network).

#### 3.4 Regulatory framework for patients' summaries

Hungary doesn't have legal provisions in the area of patients' summaries. In the contrary the Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest, do not support such solutions. According to the view of the data protection professionals patients' summaries have not shown exact purpose for the processing of personal data. On the other side most of such data (e.g. blood group) should be examined in all necessary cases.

The experts do not see any possibilities of the implementation, however it is technically possible. There exist special card systems with such summaries in case of some diseases.

### 3.5 Regulatory framework for telemedicine

There are no specific provisions in Hungary with regard to telemedicine. On the other hand, if the rigorous data protection rules are not violated there doesn't seem to be major legal obstacles to practice telemedicine in Hungary.

Document ref.: ....... INFSO\_eHealth\_Legal/HU-Profile Page: 16 of 36



Page: 17 of 36



### Study on Legal Framework of Interoperable eHealth in Europe

Numerous, mainly point to point pilots are know in Hungary. [RD4] is mentioning one of them: from 2003 "Virtual Information Space for Health Care is a telemedicine system developed and implemented by the Company Applied Logic Library. The main objective of this system is provision of health care providers with unified virtual information space and a virtual distributed telemedicine services. The basic concept behind the system is the Virtual Electronic Patient Record. It seems that current implementation scope is limited." ...

# 3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions, however, the paper form is strictly regulated by the Act CLIV of 1997 (form, signature, stamp etc). For most of the prescriptions, in particular for prescribing pharmaceuticals to the ambulatory patient, it is not possible to use electronic means to transmit a prescription for lack of the necessary infrastructure.

### 3.7 Overview of relevant legislation

The systems are regulated by laws and regulations, from the Constitution to various governmental and ministerial decrees. Most of such orders and decrees, however, mean heavy, regular administrative burdens for the health services providers. The administrative burdens can be resolved by the means of eHealth.

Currently eHealth does not exist explicitly in the Hungarian legislation. However, laws and ministerial decrees regulate the reporting obligations in stated cases. The reports about the reimbursement of medical treatments by the NHIFA are mainly in electronic form The historical background of the legislation is the following [RD5]:

"The Act XX of 1949 the Constitution of the Republic of Hungary declared health to be a fundamental right for which the state was held responsible. Throughout the communist period this was interpreted to mean that the state was exclusively responsible for both the financing and delivery of health services.

Although Act II on Health of 1972 confirmed that access to health services was a right linked to citizenship and promised comprehensive coverage free-of-charge at the point of use, an increasing gap developed between rhetoric and reality. The system was suffering from excess capacities, deteriorating service quality and widespread informal payments at the same time. The need for radical health care reforms became increasingly apparent in the 1980s. The Social Insurance Fund was separated from the government budget (1989). The financing of recurrent costs of health services were transferred to the Social Insurance Fund. The 1989 amendment to the Hungarian Constitution defined the principles and basic democratic structure of the new republic, the framework in which the health care system operates."

Concerning eHealth the national legislation in Hungary addresses the following issues: data protection, electronic communications (with regard to data protection and confidentiality) and digital signatures. Relevant legal acts are enlisted below with the link of the English texts, when available:

Document ref.: ......... INFSO\_eHealth\_Legal/HU-Profile



### Study on Legal Framework of Interoperable eHealth in Europe

- Act LXIII of 1992 on Protection of Personal Data and Disclosure of Data Public Interest, includes changes made by Act XIX of 2005.
   <a href="http://abiweb.obh.hu/dpc/legislation/1992\_LXIIIa.htm">http://abiweb.obh.hu/dpc/legislation/1992\_LXIIIa.htm</a> and Act XLVII of 1997 on the Handling of Medical and Other Related Data;
- Act C of 2003 on electronic communications (not relevant amendment for our topic in 2007) <a href="http://www.nhh.hu/dokumentum.php?cid=10617&letolt">http://www.nhh.hu/dokumentum.php?cid=10617&letolt</a>;
- Act XXXV of 2001 on Electronic Signatures http://www.nhh.hu/dokumentum.php?cid=10623&letolt amended in 2004;
- Act CVIII of 2001 on certain issues of electronic commerce services and information society services: <a href="http://www.nhh.hu/dokumentum.php?cid=11961&letolt">http://www.nhh.hu/dokumentum.php?cid=11961&letolt</a>

Indirectly relevant are further laws: *Act LXXXIII of 1997 on the Services of Compulsory Health Insurance*) relating to social security and the use of the social security identification number (TAJ) and Act XX of 1996 on the identification methods and codes instead of the personal identification number, or *Act CLIV of 1997 on Health*.

Document ref.: ........... INFSO\_eHealth\_Legal/HU-Profile Page: 18 of 36





# 4 Regulatory framework for the healthcare profession

The Hungarian monograph of [RD14] is not available. Instead of we use the detailed collection on the most important legislation in force of the Hungarian healthcare profession from the portal of the Ministry of Health

http://www.eum.hu/main.php?folderID=3738&objectID=5005132 (only in Hungarian). [RD5] on pp. 123-141 provides a list of the regulation of the years1949-2003.

Act CLIV of 1997 on Health is the basic and most the comprehensive legislation in the sector. The act:

- sets up the general framework for healthcare including patient rights, the organization of the health care system, major actors and responsibilities for health care (Article 143).
- establishes the institutions of patient right representatives (Article 30-33), mediation (Article 34), hospital supervisory councils (Article 156, section 1-5) and hospital ethical committees (Article 156, section 1-2, 6-7)
- establishes the National Health Council (Article 148, 149)
- introduces the National Health Promotion Programme, to be approved and supervised by the Parliament (Article 146)
- determines the services which have to be financed from the national government budget (Article 142, section 2, high cost, high tech interventions point d)
- establishes the Healthcare Professional Training and Continuing Education Council (Article 117)
- confirms national institutes to assist the Minister of Health (Article 150)
- defines maintenance obligation (Article 155, section 2)
- utilization according to the principle of "appropriate level of specialization" or "progressivism" (Article 75, section 3 and Article 76)
- efficient use of resources (Article 75, section 4)

The other important acts, including some regulations are the following in chronological order:

Act XI of 1991 on the National Public Health and Medical Officer Service and Decree No. 362/2006. (XII.28) of the Government on the National Public Health and Medical Officer Service and on the assignation of the Pharmaceutical Public Administration Authority

- the Service is established as a state agency on the basis of the former public hygiene stations, but tasks are defined according to the concept of modern public health, and include the professional supervision of health care
- defines the structure and organs of the National Public Health and Medical Officer Service (hereafter NPHMOS)

Act XCVII of 2006 on the Professional Chambers in the Healthcare

- the system of the Chambers
- the Chambers are given the right to make decesions in ethical offences;
- the minister has the right of the supervision of the Chambers

Document ref.: ....... INFSO\_eHealth\_Legal/HU-Profile Page: 19 of 36 Version:......v1.1





Act XLVII of 1997 on Management and Protection of Health Care and Related Personal Data

- protects confidentiality of personal information in health services

Act LXXXIII of 1997 on the Services of Compulsory Health Insurance and its executive order of Government Decree No. 217/1997. (XII. 1.) Korm.

- determines the in-kind and cash benefits of the social health insurance, and the rules of their utilization
- declares the responsibility of the state to provide services, regardless of the revenues of the HIF (Article 4)
- defines services, which are excluded from social health insurance coverage (Article 18, section 4-6; high cost, high-tech interventions
- Article 18, section 5, point g), which can be utilized with co-payment (Article 23), and whose price is subsidized (Article 21)
- defines to rules of utilization and the referral system (Article 18, section 1-3; Executive order, Article 2)
- rules of contracting (Article 30-33, and Executive order Article 13-25), control of implementation of the contracts (Article 36-38)
- determines methods of payment in general, and that the HIF covers recurrent costs of services only (Article 34-35)

Act II of 2000 on Independent Medical Practice

- practising family doctors are granted a right to practice which can be sold and bought Act CXVI of 2000 on Mediation in Health Care and Joint Decree No. 4/2001. (II. 20.) EüM-IM of the Minister of Health and the Minister of Justice on Certain Aspects of Mediation in Health Care
  - establishes the institution and procedures of mediation to resolve disputes between patients and health care providers without going to court

Act VI of 2002 on the Convention of the European Council for the Protection of Human Rights and Dignity of Human being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine and on the promulgation of the additional protocol to the Convention for the Protection of Human Rights and Dignity of Human being with regard to the Application of Biology and Medicine, on the prohibition of cloning human beings

Act LXXXIV of 2003 on the Various Aspects of Practicing Medicine

- regulates the various employment options for health workers Act CXXXII of 2006 on the Development of the Healthcare System

#### 4.1 Legal conditions for the practice of healthcare

The several times amended Act CLIV of 1997 on Health is regulating the practice of healthcare in Hungary. Healthcare service can be provided only with the possession of a licence and according to the prescriptions of it. The licence can be released only in the case, when the provider has liability insurance. Article 110 regulates the personal conditions: Health workers are: the doctor, the dentist, the chemist, the person with other higher healthcare qualification (e.g. clinical psychologist) the person with healthcare qualification (e.g. nurses, midwives), and collaborating persons without qualification.

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



A person can provide health service in the case when:

- a) she or he has the determined healthcare qualification or specialised high level qualification
- b) she or he is registered (basic register of qualified persons, functional register, etc.) Persons of other states can get temporary licence from the health authorities without registration in the case of suitable qualification and for the interest of the patient care. The authority guides a separate register about these persons.

All person who is acquired a health qualification in an educational institution acknowledged by the state in Hungary (or acquired abroad and naturalized or acknowledged in Hungary) figures in the basic register.

Getting into the basic register happens automatically; the Office registers the persons obtained a qualification at an institution (or from the naturalisation/decision being about an acknowledgement) based on data sent over by an institution issuing the diploma or the decision about an acknowledgement, and sends a justification from this direction for the persons obtained the qualification.

The justification implies the person's basic registration number, which is single the number of the medical stamp in the case of physicians. (The rubber stamp himself is made by the NHIFA, and it can be obtained there).

After getting into the basic register one can apply for the registration into the function register by an application submitted for the Office of Health Authorisation and Administrative Procedures (hereafter Office). One of the conditions of the registration into the function register is the entry in the basic register of persons with health qualification.

Paragraphs 1-3 of Art. 110 of Act CLIV of 1997 on Health regulate who should register themselves into the function register.

Accordingly health activity might be fulfilled by a person having special qualification for that activity (medical, dentist's, chemist degree; clinical academic specialisation psychologist diploma), and registered in the function register.

The Act on Health makes a difference between activities which can be made independently and which can be made under supervision. Health activity can be made independently by a person having a valid qualification (with a special examination) on the given area

A person can make supervised activity who is participating in a necessary education for the acquisition of his/her qualification or person deleted from the function register (in cases like this in the interest of him/her getting back into the function register, it is needed for it until necessary time beside supervision to work) under the supervision of a person with special examination.

It is necessary to collect 250 credit points under a professional development period, that the Office renew the petitioner's function registration for another five years.

The time span of the professional development period is five years, the beginning of which is the day of the registration in the function register.

The collection of credit points is regulated by 52/2003. (VIII.22.) EszCsM on the continuing education of doctors, dentists, chemists and clinical academic specialisation psychologists. Based on this everybody should collect credit points who entered the function register. The summation of credit points obtained in the professional development is issued by the

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



Page: 22 of 36

### Study on Legal Framework of Interoperable eHealth in Europe

secretariat of continuing education at the university leading the professional development of the person. The summation of points implies the practical and theoretical credit points collected under the five-year cycle of the function register.

Healthcare providers must obtain a licence to practice from the National Public Health and Medical Officer Service (NPHMOS, in Hungarian ANTSZ), which maintains the registration database. The minimal professional conditions for 124 cases are regulated in ministerial order. <a href="http://www.antsz.hu/portal/oldalak/ugy.page?id=e9284c59-830c-11db-aa79-8df5ba03d2a2">http://www.antsz.hu/portal/oldalak/ugy.page?id=e9284c59-830c-11db-aa79-8df5ba03d2a2</a>
Before issuing the licence to any provider, medical officers inspect the facilities and ascertain whether the minimal building, healthcare requirements, personnel and material standards are fulfilled Separate or special rules apply to a number of services, such as primary care, home care, patient transfer, emergency ambulance services), human fertility treatment sterilization procedures) and organ transplantation. The provision of non-conventional medical treatment is also regulated including the scope of activities, and educational, infrastructure and administration requirements.

Pharmaceuticals and medical devices, including medical aids and prostheses, fall under a registration and licensing system administered by the National Institute of Pharmacy and the Authority for Medical Devices of the Ministry of Health. Prescription and prices are also regulated, including the wholesale and retail price margins, but these regulations do not apply to pharmaceuticals purchased by healthcare providers

Both registration and licensing systems have recently been harmonized with the practice of the European Union.

### 4.2 Control over the practice of medicine

The NPHMOS (ANTSZ) practises vocational supervision above the healthcare providers and services. In the vocational supervision's framework the ANTSZ's task the health sectoral measures, and the check of the success of the application of the vocational rules. Regular monitoring of providers includes checking personnel and material, minimum standards and the quality of provided services. The system consists of supervisory chief medical doctors at the municipal level for primary care, and at the county and in some cases regional level for various medical specialties. The county and municipal chief medical officers appoint supervisor chief medical doctors, in collaboration with the professional colleges and national institutes of health.

Quality assurance is supervised mainly by two authorities. OSZMK (Nationat Centre for Healthcare Audit and Inspection) is responsible for monitoring on site with close cooperation with providers, while Health Insurance Supervisory Authority acts as health consumer protector and also disseminates quality indicators.

The healthcare employees general vocational, rather ethic (in the following: ethic) rules are developed by the National Ethical Council (OET) with the participation of the professional associations (first of all the Chambers) and it is approved by a ministerial decree. Furthermore OET is conducting proceedings opposite the healthcare employees in defined vocational-ethic cases. In general the County Ethical Councils (METs) work in the ethical proceedings.

Document ref.: ...... INFSO\_eHealth\_Legal/HU-Profile



#### Study on Legal Framework of Interoperable eHealth in Europe

The membership of the Hungarian Medical Chamber was compulsory for practicing physicians and dentists in the years 1994-2006. The Chamber defined the structure, tasks and responsibilities of the medical chamber, including issuing a code of ethics for medical practice. The Chamber can discipline those who violate its rules.

Nowadays the rules of association change also for physicians, pharmacists and nurses. As the experience of the last 10-15 years showed, mandatory membership distorted the behaviour of these associations, because the large number of involuntary members could not influence the decisions of the more-or-less self-appointed leaders. Thus, mandatory membership is abolished from 2007 onwards, which will probably open the door for many new organizations in all the three above mentioned professions. However, the Ethical Commissions of the Chambers lost their general possibilities.

## 4.3 Professional liability

The disciplinary liability covered by the professional obligations regulated by the law and the ethical codes. See the previous point.

All healthcare providers are obliged to be covered by liability insurance to enable them to compensate patients appropriately in justified malpractice claims in Hungary. The hospitals as healthcare providers are involved in most cases in liability trials, not the doctors itself. Since 2000 exists the mediation in the healthcare.

# 4.4 Professional secrecy

One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician. (The definition of medical secret by the law is the following: the health and personal identification data learned by the data processor in the course of the medical treatment, other data concerning with the necessary medical treatment, with the in a process or with the finished medical treatment furthermore recognized in connection with the treatment).

Article 25 of the act CLIV of 1997 on the Health defines the medical secrecy as the patient's right. Article 138 prescribes that the professional secrecy is obligatory. Any employee of the healthcare provider has a legal obligation not to disclose confidential information concerning a patient which he learns in the course of his professional practice.

The obligation of non-disclosure applies not only to information acquired directly from the patient, but also to information concerning the patient which the doctor learns from other sources. That means also: all the members of a medical team are obliged to respect the confidentiality of the patient's information. The act XLVII of 1997 on the Handling of Medical and Other Related Data accepts that this information may circulate within the team (so-called "shared medical secret", see later).

Document ref.: ......... INFSO\_eHealth\_Legal/HU-Profile





# 5 Processing of personal health data

### 5.1 Short overview of personal data protection legal framework

Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest regulates the manual and automatic procession of personal data. It has been amended in order for the compliance with Directive 95/46/EC of the European Parliament and of the Council. More over there is Act XLVII of 1997 on the Handling of Medical and Other Related Data regulating the detailed cases of data collection and processing in the healthcare sector.

From a study made by the team of the first data protection commissioner of Hungary (<a href="http://www.ekint.org/ekint/ekint\_angol.news.page?nodeid=189">http://www.ekint.org/ekint/ekint\_angol.news.page?nodeid=189</a>) in 2007, we take over the following key findings:

"The protection level of the personal data, the system of the protection, and its constitutional requirements in member states of the European Union are different. Since the documents concerning the protection of personal data legislation on the union level are implying only the minimal rules. The Hungarian data protection level was influenced a minimal measure only by the transposition of European Directives, since in our homeland the level of the data protection – characteristically onto the countries of post dictatorship – is very high and satisfied the minimal rules before the accession to the Union already."

"Two of the interpretations of the personal data are known in the European right. In the absolute interpretation the information is personal data until, as long as it is possible to get from it to the data subject without respect to the used resources. According to the relative interpretation the personal data is that information, which the given data controller able to personalize so to one single person. The text of the Hungarian law stands rather on the soil of the absolute interpretation, in contrary of some statements of the data protection commissioner and some judicial decisions, which leads to absurd results many times."

The basic principle of the data protection is the right of informational self-determination. The data subject should consent, should be informed and have control above his data. The main concepts to be considered at of data processing: defined purpose, data avoidance, the prohibition of data reserving, distributed information systems, information about the purpose, and the change of the purpose.

Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest (in English:

http://abiweb.obh.hu/dpc/index.php?menu=gyoker/relevant/national/1992\_LXIII) is very similar to the European directive in its content.

#### 5.2 Transposition of article 8 of Directive 95/46/EC

Generally speaking Act LXIII of 1992, the Hungarian data protection law is transposing article 8 of Directive 95/46/EC in the definitions of special data and in its article 3 with the

Document ref.: ......... INFSO\_eHealth\_Legal/HU-Profile



### Study on Legal Framework of Interoperable eHealth in Europe

prohibition of processing such data, giving the exceptions for this. The rigorous character of the data protection law make necessary to regulate by law the conditions of processing data concerning health in details by the Act XLVII of 1997 on the Handling of Medical and Other Related Data. The act defines separately the data related to health, and to the data of personal identification, and the medical secrecy. Later covers both.

Article 4-5 Formulates that purposes of healthcare in cases when the processing is allowed

Article 7-14 Defines data processing rules of medical treatment

Article 15 Defines data processing rules of sanitation and epidemiology

Article 16 Defines data processing rules of public health

Article 17 Defines data processing rules in case of education of health professionals

Article 19 Defines data processing rules of epidemiological analysis

Article 20 defines the rules of statistical data processing in the health sector both domestic and international purposes.

Article 21 Defines data processing rules of scientific research

Article 22 Defines data processing rules of the institutions of social security

Article 22 A-C Defines data processing rules of the organizers of medical treatments

Article 23 -27 Defines data processing rules of data transfer outside of the healthcare sector

Article 28 -24 about the registration of data related to health, and to the personal identification

There are large lists with the diseases and screenings concerning obligations of reporting personal data in the supplement of the act.

### 5.3 Information and access rights of data subjects

In general Art 11-12 of the data protection law, concerning health Art. 7. § 3-7 and Art. 11. § 1-2 of Act XLVII of 1997 health data protection law adds specific provisions on the right of the data subject (and in case his death for the representative) to access personal data. However, such rights are regulated in art.24 of Act CLIV of 1997 on Health in the relation to the rights of patient to get knowledge of his health documentation (i.e. patient record, which naturally contains personal data).

#### Article 11.of Act XLVII of 1997

- (3) The data subject "entitled to get information from the data processor related to the medical treatment, gets to know the health and personal identification data concerning him, may look in into his health documentation, and from them onto his own expense may receive a copy.
- (4) The right according to paragraph (3) is the due
- a) Under the time span of his treatment by way of a written authorised person
- b) Following the conclusion of his treatment by way of a person authorised in a private agreement with full probative value."

### 5.4 Other relevant rules regarding personal data protection

There are eight acts in the Hungarian legislation concerning data protection onwards the Constitution to the Criminal Code <a href="http://abiweb.obh.hu/dpc/index.php?menu=gyoker/relevant/national">http://abiweb.obh.hu/dpc/index.php?menu=gyoker/relevant/national</a>. The two relevant for health was mentioned above. However, the act on health, the ethical regulations (ministerial decrees), and the act on the social insurance and about the insurance number (TAJ) all

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



# Study on Legal Framework of Interoperable eHealth in Europe

contains rules regarding personal data protection. The professional chambers and associations have their own regulations.

It should be mentioned the act LXIII of 1992 on registration of personal data and address of citizens, and the act XX of 1996 prohibiting the general use of the personal identification number and introducing the sectoral identifiers, e.g. the TAJ, tax number, etc..

On the institutional level every data controller and processor should have his own data protection regulation and registers according the data protection act. Every processing before the beginning of the registration should be reported to the data commissioner. The data commissioner is controlling before and regularly the compliance of the individual registers or databases containing personal data.

Document ref.: ...... INFSO\_eHealth\_Legal/HU-Profile





# 6 Rights and duties of healthcare providers and patients

Rights and duties of healthcare providers and patients are regulated extensively in the Act CLIV of 1997 on Health (with the latest amendments and executive decrees)

The act has established:

- Institutions for the safeguarding of the rights of patients and for resolving disputes, namely the patient rights representative and arbitration.
- Introduced the concept of waiting lists, and ordered priority setting without discrimination, on the basis of uniform and explicit criteria, taking into account the health status of patients. There are two types of lists, a central one (for transplantations) and another one maintained by all the hospitals individually. The Health Insurance Authority will monitor these lists and will have the power to intervene, if the complaint of a patient is justified.
- Regulation of the behaviour of health care workers including rights, duties and ethical considerations.
- The provision of non-conventional medical treatment is also regulated including the scope of activities, and educational, infrastructure and administration requirements

### 6.1 Scope of the law

"The scope of the law covers a) all natural persons staying, b) health care service providers working, c) and health care activities provided on the territory of the Hungarian Republic". Patient means" the person employing or sharing in the health care provision" Health care service provider means: "independently of the form of property and from the maintainer all individual health care entrepreneur, legal entity or organization without a legal entity entitled for the providing health care service based on the licence issued by the health care authority".

Health care service means "the complex of health care activities which can be provided in the possession of a licence issued by the health care authority, is aimed at a patient's examination and treatment, onto his nurture, onto his nursing, onto his health rehabilitation, onto the reduction of the pain and the suffering, furthermore in the interest of the above ones is aimed at the processing of his examination substances, included the activities concerning the provision with medicaments, medical aids, therapeutic supplies according to separate regulation, and the rescue and the ambulance service, the obstetric supply, the special procedures being aimed at the human reproduction, the surgical infertilesation, the medical science researches made on the human, furthermore the medical procedures of the dead examination, the procedures with the dead persons, including the related measures - according to separate regulation - with regard to the dead persons' transport, in order to preserve the health of the individual, furthermore the prevention, the early recognition, the statement, the treatment of illness, the averting of mortal danger, the improvement of the condition resulted by the illness, the prevention of the additional decay of condition of the patient."

#### 6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is specified in details in art. 26 of the law: the patient should give all information for the healthcare workers concerning his illness, about his

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile





previous treatments, illnesses, etc. and keep himself to their instructions, observe the regulations of the institution.

### 6.3 Right to quality care

Art. 7 of the law determine the right to the suitable, continuously accessible care on the basis of the principle of equal treatment among the patient's rights. The measures of the quality care are prescribed in the article 75-76 of the law, about the operational principles, and in the Regulation. Art. 119-123 are about the quality assurance system and the quality audit of healthcare providers.

# 6.4 Right to free choice

According to article 8 the patient has the right to free choose the healthcare provider and the physician. The right to free choice is determined by the restriction to the place of residence on the primary level. However, the patient can choose freely his family doctor in the towns, in contrary of little villages, where is only one doctor in the area.

### 6.5 Rights related to information about the state of health

A patient has the right to receive entire information in individual form: about his state of health included its medical judgement, about the medical examinations, the results of the examinations, etc. Communication with the patient must take place in clear language, adapted to the individual needs. (Art. 13-14)

#### 6.6 Right to give consent

Article 15 of the law handles with the patient's self-determination. In the framework of the right of self-determination the patient may decide freely whether he wishes to take advantage of medical care, in the course of care he may agree or reject the treatments in written form. The consent has to be recorded and added to the medical records.

# 6.7 Rights related to the patient's medical record

The patient has the right to get know of his whole health care documentation (Art. 24). The documentation should be archived for 30 years, (PACS and similar records for 50 years). The content of the health care documentation (medical record) is prescribed in article 136. It can be kept in paper or in electronic format. Nowadays the documentation is prepared in both formats, because the doctor should sign the partial records several times. The summary of the documentation should be given to the patient at the end of the healthcare process.

### 6.8 Right to protection of privacy and intimacy

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health. They have also a right to the protection of their intimacy. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent. (Article 10 about the right to human dignity, and art. 25 on the right to medical secrecy)

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile

Page: 28 of 36



# Study on Legal Framework of Interoperable eHealth in Europe

# 6.9 Right to representation in case of incompetence

The law contains rules to protect the rights of patient who are legally or factually not capable of exercising their rights as a patient. Act 11 prescribes the rights to keep connection, the representation of incapable patients, etc.

Document ref.: ........ INFSO\_eHealth\_Legal/HU-Profile



Page: 30 of 36



### Study on Legal Framework of Interoperable eHealth in Europe

# 7 Identity management in the health sector

The identity management system of the NHIFA based on the SSIN/TAJ is general due to the centralized compulsory insurance system. In point 6.7 we referred to art 136 of act CLIV of 1997, which order to indicate the personal identification data of the patient in the healthcare documentation (i.e. medical records). The healthcare providers are using primary the date of birth and the name of the patient in the registers. The information in this chapter is based on our IDABC-report referenced under [RD9].

The traditional identity infrastructure can be said to consist of centrally kept but distributed, locally maintained paper and electronic registers for natural persons and on county level maintained for legal persons, and there is a family of personal identification documents in bankcard format to natural persons.

#### 7.1 Overview

The central unit of the population register system - containing the personal and address data of natural entities - is managed and operated by the Central Office for Administrative and Electronic Public Service (Közigazgatási és Elektronikus Közszolgáltatások Központi Hivatala (hereafter KEKKH) - (<a href="http://www.nyilvantarto.hu">http://www.nyilvantarto.hu</a>; available in Hungarian) who also supervises the regional and local databases. KEKKH is responsible for generating the unique personal identifiers, and issues the ID cards, together with a number of other identification documents and the passport. Since the 1st of January 2000, the Office has been issuing certificates with an ID1 card format, which will provide an easy changeover to the eID tokens by the integration of chips.

According to the legislation in force, there are three documents that can be used to prove identity; these are the ID, the passport and the driver's licence.

The personal identifier linked to the population register can only be used to a limited extent, excluding the incorporation of this identification number in the digital certificate or any other document, with the exception of the address card. Separate official certificate must be issued for all identification codes defined in the basic registers. An official certificate may contain only a single identification code; however it is valid only together with an identification document. Thus, public administration in Hungary currently uses the following cards and registers

- Personal identification document (ID) (card or a paper booklet from the age of 14) and
- Official personal identification and address certificate (address card with the 11 characters personal identifier)
- Official certificate for verifying social security number Social security card with a 9 digits Social Security Identification Sign (TAJ number)
- APEH tax certificate Tax card with the tax identification sign (10 digits)
- The student card should be included in this list, which for those under the age of 14, subject to compulsory schooling, besides providing certain benefits, also serves as proof of identity.

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile



Page: 31 of 36

### Study on Legal Framework of Interoperable eHealth in Europe

Identification information with regard to legal persons is primarily stored in the so called Company Register, which identifies legal persons (and natural persons – entrepreneurs) by the so called enterprise number.

#### 7.2 The SIS Card

The Social security card with the 9 digits Social Security Identification Sign (hereafter TAJ number)

The TAJ number is a personal identifier issued for every Hungarian citizen after birth, for life long in the normal case. The NHIFA generates the TAJ number. Foreign citizen can get a TAJ number in case of an insurance relationship or agreement for health services.

The official certificate of the TAJ - the TAJ card (Certificate of entitlement for health services) – is needed for the health care services supported by the NHIFA.

<u>The official TAJ number certificate</u> is issued and delivered to the bearer by the NHIFA in form of a paper token (SIS card). The official card (certificate) contains:

- a) Family name and given name,
- b) Date of birth,
- c) TAJ number, and
- d) The seal of the issuing body and the signature of the issuer.

The endeavour for the use of smart cards (ICC) has been present at the earliest in the Hungarian health sector. During the years a number of projects and experiments have been carried out. The Hungarian Chamber of Doctors (Magyar Orvosi Kamara, MOK) issued the first multi-functional, professional doctors' card already equipped with PKI capabilities in conjunction with a bank. The Multifunctional Smart Card for Doctors (MSDC) combined the functions of payment credit card with other options like practice licence, storage of educational and qualification data, digital signature, insurance and health services related functions. Cards of this type were planed to issue for 40000 medical professionals. The data of the subjects were transferred to and processed by the card issuer bank without their previous consent, which violated the data protection act. The second generation of MSDC, without the bankcard functions was ready by 2006. MSDC is perceived as a starting point for a new card system planned within future Hungarian Health Care Projects. The first one was the pilot project of the NHIFA.

The compulsory introduction of the European Health Insurance Card by 2008 provided an impetus for the NHIFA, to extend the application of their PKI based identification and signature applications developed for their internal use and for health service providers by the introduction of multi-functional cards to replace the TAJ cards (social security identification cards). However, these plans are not being implemented in 2007 either, due to the shortage in public funds. Nowadays the plans for the issuing of the eHealth cards were accepted in the Ministry of Health, and the planed decree was ready in the spring of 2008. At the end of September 2006, a three months pilot project was completed successfully by the NHIFA . <a href="http://www.oep.hu/pls/portal/docs/PAGE/SZAKMA/OEPHUSZAK\_INFOSZOLG/DEVELOPERS">http://www.oep.hu/pls/portal/docs/PAGE/SZAKMA/OEPHUSZAK\_INFOSZOLG/DEVELOPERS GUIDEOK 1.01.PDF</a>

The experiment was carried out in three of the western counties of Hungary, with the participation of 9 family doctors, 12 workstations of 4 hospitals and the 16 thousand potential

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile





patients covered by them as well as the pharmacies operating in their area. The doctors used their professional cards, and 11370 insured people received insurance cards. The insured people participating in the experiment could manage the electronic transactions related to e-E-prescriptions and E-admittances, E-travel vouchers. The participating doctors made out close to 3000 prescriptions during the three months period, and registered more then 2 thousand patient admittances and releases.

The new, multi-functional experimental card used in the project contained all together the data of the TAJ card, the European Health Insurance Card, the Pensions Card and the data required to access the Client Gate (digital PKI certificates on the long term), thus this card is suitable for the verification of eligibility both in Hungary and the EU member states. There isn't any likelihood to take up health data, such as patient summaries on the card recently. The assets utilised allow the electronic identification of the insured persons arriving from the EU countries with similar cards.

#### 7.3 Patient identifier

Personal identification document is used for the identification. All citizens were assigned a TAJ number. This identification system covers the whole population, without taking into consideration of the eligibility of the citizen. The TAJ number is currently printed on paper-based insurance card which is valid together with the personal identification document. As noted above, identification of the patients is primarily based on the name and date of birth at the registers or databases of the health care institutions, however nowadays all documentation contains the TAJ number, too.

#### 7.4 Authentication of healthcare professionals

There is not any Certified Public Register in Hungary which can yield the basis of authentication.

All health care professionals working in health care should register at the Office of Health Authorisation and Administrative Procedures, which issues a document certificating it. The registered data are handled in various central registers, which can cause a non-consistency with time passing:

- The NHIFA registering the physician with the same data issues a stamp with a registration number, and the doctor is eligible to ask for printed prescription forms for his insured patients with his own identification data, bar code etc.
- The register of the Healthcare Professional Training and Continuing Education Institute and the Office of Health Authorisation and Administrative Procedures follows the credit points of professional trainings.
- The registers at the NPHMOS, etc.

The objectives 7 and 8 of the new eHealth strategy are the harmonisation of central registers and building Certified Public Registries.

Hungarian Medical Chamber has his own register, which was the basis of the first professional cards helping the authentication. Recently the register of the Chabers can not be general after the repeal of the obligatory membership...

Document ref.: ......... INFSO\_eHealth\_Legal/HU-Profile



Page: 33 of 36

#### Study on Legal Framework of Interoperable eHealth in Europe

### 7.5 Exchange of health-related data

The health-related data are communicated basically in paper form and mainly in a point-to point system between the doctors or health care providers. The main obstacle is the lack of the spreading of electronic signature, without the needed authentication of healthcare documents is impossible.

The compulsory reporting aiming the reimbursement of medical treatments by the NHIFA, or aiming the epidemiology and public health for the NPHMOS is regulated by ministerial decrees.

The information systems of NHIFA are using floppy discs or on-line connections for the transfer of the reimbursement and the statistical data since a long time ago:

The Dsend electronic data reporting of medical attendance was one of the first and largest nation-wide applications in Hungary.

The Dsend system provides electronic means of reporting the data of medical attendance for hospitals, health institutions, family doctors, and other health service providers. Using electronic signatures the application assures the integrity, authenticity and cryptographic security of the transmitted data at a high level.

The partner side users can connect to the closed messaging system through special client program with the use of a private organisational type advanced electronic signature certificates acquired from the authorised Certificate Service Providers. The entitlement management is carried out by a central management system on the server. The system uses time stamps issued by official time stamp service providers. The validation of the electronic signatures on the message packets is verified online.

The client program provides an XML based file able to contain several documents compiled into a single unit of the data to be sent or received.

Nowadays all hospitals of the country are connected to the system. A recent project is developing the client program for the family doctors.

Document ref.: .......... INFSO\_eHealth\_Legal/HU-Profile Version: .......v1.1



### Study on Legal Framework of Interoperable eHealth in Europe

# **8 Electronic prescription**

The activities related to e-Prescription covered development of a prestandard for ePrescription messages. Independently from this, the NHIFA pilot project of in 2006 contained an ePrescription modul. (see 7.2)

The electronic prescriptions were used only for administrative and archivation purposes not for buying off pharmaceuticals in the pilot project.

The form and rules of prescription for physicians and for dentists are regulated by the legislation. There is no relevant application of ePrescription to be mention recently.

Document ref.: ...... INFSO\_eHealth\_Legal/HU-Profile



### Study on Legal Framework of Interoperable eHealth in Europe

### 9 General assessment

The Hungarian regulatory framework is not dealing explicitly with eHealth. There is enough knowledge and interest at the professionals of the healthcare and of the ICT sectors to install and use eHealth applications when the economical and legislative conditions allow. The ICT infrastructure is sufficient, but the use of the standardized structures and of the electronic signature is negligible.

The regulation of data processing and of data transfer follows the EU Directive and the decisions of the Commission are valid concerning third countries. There are the same rules for the EEC countries as for Hungary.

The absolute character of the Hungarian data protection law does not support the simple solutions of eHealth developed in other countries as examples of best practice. We should hope that the national legislative environment and the ambitions on EU level will make possible the spreading of eHealth applications.

# Acknowledgements

The author would like to thank Péter Racskó, Ministry of Health, and György Surján, National Institute for Strategic Health Research (ESKI) for providing valuable information supporting the preparation of the national profile.

András Gerencsér

25 June 2008

Document ref.: ........... INFSO\_eHealth\_Legal/HU-Profile





# **Annex: Contact details of National Correspondents**

# 9.1 Primary Contact

Country	Hungary
Name	Andras Gerencser
Organisation	MTA ITA
Position	in charge
Mailing Address	Konkoly-Thege Miklos ut 29-33, 1121 Budapest
Work Phone	+36 - 1 - 2026584
<b>Mobile Phone</b>	+36 - 30 - 9190373
Fax	+36 - 1 - 2026584
E-Mail	agerencser@t-online.hu

# 9.2 Alternative Contact

Country	Hungary
Name	Dr. Gábor Klimkó
Organisation	MTA ITA
Position	expert
Mailing Address	Konkoly-Thege Miklos ut 29-33, 1121 Budapest
Work Phone	+36 1 392 2222 ext. 2720
Mobile Phone	+36 30 - 9220347
Fax	+36 -1- 3922242
E-Mail	Klimkoga@t-online.hu