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Study on Legal Framework of Interoperable eHealth in Europe

NATIONAL PROFILE LITHUANIA

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Study on Legal Framework of Interoperable eHealth in Europe

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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 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/200807_02-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking/

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	gp_survey_final_report.pdf , 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, http://ec.europa.eu/health-eu/doc/com2008415_en.pdf
[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 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
[RD13]	Legally eHealth, Study on Legal and Regulatory Aspects of eHealth, http://www.ehma.org/projects/default.asp?NCID=140
[RD14]	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML
[RD15]	Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf
[RD16]	International Encyclopedia of Medical Law (editor: Herman Nys), http://www.ielaws.com/medical.htm , (with country monographs)

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:
 - the permission of an authenticated entity (e.g. a person) to perform a defined action or to access a defined resource/service
 - 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

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the recognition of professional qualifications or another professional exercising 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

EHR	Electronic Health Record
....	
eID	Electronic Identity
eIDM	Electronic Identity Management
.....	
GP	General Practitioner
...	
HiT	Health in Transition
.....	
PKI	Public Key Infrastructure

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....

SIS..... Social (security) Information System

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LNHS Lithuanian National Health System

NEHS National Electronic Health System

SDPI State Data Protection Inspectorate

EHIC..... European Electronic Health Insurance Card

3 Introduction

3.1 General overview of the Lithuanian healthcare system

An overview of the Lithuanian healthcare system can be found in the Lithuanian HiT country report published by the European Observatory on Health Systems and Policies (written by Gediminas Černiauskas and Liuba Murauskienė, edited by Ellie Tragikes):

<http://www.euro.who.int/Document/E69920.pdf>

From this report, we reproduce the following important observations, however the report was published in 2000 and, thus, updates are made to the original text.

It should be emphasized that Lithuanian National Health System (LNHS) mainly covers general management of health affairs in the Republic of Lithuania, ensures social justice in health activities, integrates all health activities resources into the unified system according to the national priorities of health activities, integrates individual health care and public health care into a general system, ensures the implementation of the Health Programme of the Republic of Lithuania as well as of the state and municipal health programmes, ensures the interdepartmental co-ordination of health activities and ensures the participation of the public in the shaping of health policy.

Decentralization of LNHS in municipal, county and national levels helps to achieve the above mentioned goals.

Municipalities are responsible for the municipal level of the health care and organize primary health care. Municipalities are engaged in running small and medium sized hospitals within their localities. Primary health care is provided by diverse medical personnel in health centres, GP cabinets, dispensaries and polyclinics. Mostly primary care is understood as practice of GPs.

County administrations are responsible for the secondary health care (physicians – specialists). The patient commonly is directed to the hospital by GP or the secondary level doctor (referral system, except in case of emergency). Specialized outpatient services are provided in polyclinics and dispensaries of hospitals. In-patient care is exercised in general and specialized hospitals.

The Ministry of Health of the Republic of Lithuania administers tertiary health care, which is comprised of high specialization university clinics in Vilnius city and Kaunas city.

The health care services are provided in national and private sectors in the Republic of Lithuania. Health care system services are generally national, but the number of private health care services provided in national hospitals also arises. Many expectations are associated with the emergence of the private health care sector in the Republic of Lithuania. However, there are problems of reimbursement from the State Patients' Fund for private health care services. Therefore, the appearance of the private sector has raised many debates.

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Health care services are provided under agreements with health insurance funds. Urgent health care is provided for all residents. Other health services are available for insured persons with the main costs of treatment covered by insurance according to compulsory health insurance system, which covers 99 % of the Lithuanian population. People who do not pay compulsory contributions and are not insured by the State must cover the cost of treatment personally. In addition, voluntary health insurance is possible as supplementary to the compulsory one, however, it is still not popular in Lithuania and is used by a small part of the population with high income.

Physicians in State and municipal health care institutions are salaried. Payment for GP benefits depends on the number of persons enrolled in this list. There is a free choice of physician at all health care levels. All persons have to choose a general practitioner to be enrolled in the GP list.

LNHS is financed through compulsory insurance payments, taxable income (from national and municipal budget) and direct patient payments. Basically, health care is free of charge. State Patients' Fund pays for services to the health care institutions. There is a list of health care services, which are approved as paid services that are financed entirely from the person's own resources according to a set price list.

Since 2005, the mechanism for the regulation of the compensation for the damage done to patients' health has been set. So, since 1 January 2005 health care institutions must insure their civil liability for the damage done to patients' health.

3.2 Use of ICT in the Lithuanian healthcare sector

A recent (2007) status of the use of ICT by GPs in Lithuania 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 Lithuanian country brief, we take over the following key findings:

“In terms of infrastructure, 57% of the Lithuanian GP practices use a computer, which means Lithuania is not in very good position comparing with EU Member States average rate of 85,4%. Similar situation is with Internet connection – dispose 51.7% of practices. In the Republic of Lithuania, broadband connections are used by 32.7% of GP practices. With respect to all three infrastructure indicators, Lithuania is in lower position than average EU Member State.

There are resent data (2007) on the use of ICT by Lithuanian specialist prepared by Department of Statistics the Republic of Lithuania. However, the data differs quite a lot from European Pilot Study. Thus, it is hard to answer, which data shows the real situation in the Republic of Lithuania.

According to the data of Department of Statistics of the Republic of Lithuania, computer usage by GP practices is 26.8%, internet usage – 22.3% and broadband connection – about

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50%. This information shows that the Republic of Lithuania should be even in lower position when infrastructure is considered, however, the methodology is not given by Department of Statistics of the Republic of Lithuania, therefore, results can not be compared.

Lithuania scores below EU average not only in terms of infrastructure, but also in use of ICT for eHealth purpose. Only 38.4 % of GP practices use computer storage of individual patient data. Lithuania is in the last position (29%) when comparing EU level on computer usage in the consultation room. The use of computer during consultation is even lower (8%). Lithuania is at the end of the list regarding use of Decision Support Systems either for diagnosis of prescription purposes (13%).

Electronic patient data transfer is low among Lithuanian GPs. Lithuania is above EU average only regarding transfer of administration data to reimbursers (20.5%) (EU average is 15%) and other care providers (9.5%) (EU average of 9.7%). The tendency shows, the only sphere in Lithuania, which achieves the average EU level in electronic exchange of patient data via any networks, is health administration and its communication to health authorities and insurance companies. The rate of transfer of laboratory results or exchange date with other medical carers is low. According to the European Pilot Study, prescriptions are used in electronic exchange of patent data by 1.1% GP practices, however, Lithuanian legislation has not yet prepared any legal acts concerning ePrescription. Lithuania is planning to start using the electronic prescriptions by the end of 2010. Therefore, above mentioned data on ePrescribing does not reflect the factual situation in Lithuania”.

3.3 National eHealth strategy

An overview of the Lithuanian eHealth policy can be found in the April 2007 ERA Report “eHealth strategy and implementation activities in Lithuania” (Authors: Mariusz Duplaga, Mikołaj Leszczuk, Alicja Wirska, Sylwia Bukowczan and Anna Andrychiewicz):

http://www.ehealth-era.org/database/documents/ERA_Reports/eH-ERA_Lithuania_report_April_2007.pdf

From this report, we reproduce the following important observations, however the report was published in April 2007 and thus its updates are made according to the information provided in the webpage of the Ministry of Health of the Republic of Lithuania:

http://www.sam.lt/lt/main/sveikatos_apsauga/el_sveikata

Lithuania started to implement its own eHealth system in 2005. The eHealth system development strategy for the period 2007-2015 was prepared by the Ministry of Health in October 2007 (this document is available at http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=306637). The Republic of Lithuania is the first Baltic country, which has prepared the eHealth system development strategy for the period of 2007-2015 and has started its successful implementation. However, the implementation of the strategy has already started, it still has to be approved by the Government of the Republic of Lithuania. It is not clear, when it is approved and whether

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there are amendments to the strategy before it is approved by the Government of the Republic of Lithuania.

EHealth Strategy is divided into three stages:

Within the first stage (until 2011) the main functions, support facilities and infrastructure of the National electronic health system (NEHS) will be prepared. According to eHealth Strategy, within the period of three years all Lithuanian healthcare institutions will have access to NEHS services and possibility to integrate their own local information systems, the systems for electronic prescription and exchange of data in the fields of laboratory and instrumental investigations, systems of initial data collection and exchange will be implemented. Moreover, instruments for eReimbursement and statistical reports generation will be integrated into NEHS. A specialized portal for patients, physicians and eHealth specialists will be created.

It is expected that no less than 20% of patients' visits will be registered in the eHealth record system, and no less than 20% of Lithuanian healthcare institutions (including all institutions serving no less than 10 000 patients annually) and 30% of GPs would use this system in 2010. Within the period of 3 years, no less than 5% of Lithuanian residents would use eHealth communication systems; no less than 95% of compensated medications and no less than 20% of other medications would be prescribed using the ePrescribing system.

At the second stage (until 2014) the majority of GPs institutions, primary health care institutions and other healthcare institutions are expected to use the EHR system and have access to the NEHS client services. In 5 years' time, all functions of data exchange in the fields of laboratory and instrumental investigations should operate, including the possibility to exchange the visual data. The statistical data collection and eReimbursement functions should operate fully, and eHealth system would be enriched with the solution assistance, patient observation and telemedicine instruments. Until January 2014, 50% of prescription medicines would be prescribed using the ePrescribing system, no less than 20% of residents would be using direct eHealth system services and all sick-lists would be issued through eHealth instruments.

The third stage (until 2016) of eHealth services development in Lithuania foresees the universal use of eHealth information tools by patients, GPs, primary health care institutions and hospitals, including the use of IT solutions for complex research and diagnosis solutions, as well as for management of healthcare system. The quality supervision and data archive solutions would be given greater attention, and the Lithuanian eHealth system would be prepared to be integrated into the European eHealth system.

Creation of common, user-friendly information sphere for Lithuanian residents, patients, physicians and healthcare administrators is the main focus of the vision of eHealth system development strategy in Lithuania.

The mission of eHealth system implementation in Lithuania focuses on better accessibility, quality and continuity of healthcare services for country residents through implementation of information and communication systems. It is expected that these processes would lead to

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higher level of citizens' awareness and involvement in protecting their health; as well as more effective use of available resources for provision and expansion of healthcare services, based on modern IT technologies.

At the moment the Ministry of Health of the Republic of Lithuania is implementing the project "eHealth services", which aims at creating the international standards based National electronic health and healthcare records system. This project is one of the stages in the development of NEHS. It includes the implementation of the base hospitals' information system in three regional healthcare institutions (in Kaunas, Klaipėda and Vilnius) and integration of these systems into NEHS. The project aims at implementing hospitals' information systems as part of NEHS corresponding to all international standards and covering the whole territory of Lithuania. NEHS will enable faster exchange of the data on patients' treatment services, procedures and lab tests results among healthcare institutions. In addition, it will provide more opportunities for healthcare institutions to solve their clinical and resource allocation objectives as well as to participate in the research projects and use their results in practice.

Establishment and development of an electronic health record (EHR) is one of the most important development directions foreseen in the NEHS development strategy for the period of 2007-2015. Patient-needs-oriented EHR aims to assure lifelong and effective provision of healthcare services. EHR is being developed gradually, i.e. during the first years it will carry only the critical patient health information and later it will be supplemented with more detailed medical data. At the end of EHR implementation the whole information will be processed automatically, used for clinical decision support and available to authorized users.

Only reliable and operational NEHS infrastructure, designed to accumulate EHRs and to ensure data exchange among the healthcare institutions, will enable successful functioning of EHR in Lithuania. Information systems of healthcare institutions integrated into NEHS will allow creation, storage and transfer of EHR according to the principle "one resident – one EHR".

The automation of internal processes in the largest country's healthcare institutions will allow more convenient patient registration and management, administration of bed occupancy, registration of inpatient EHR, collection of data about patients' nursing and other clinical information; implementation and optimization of orders; storing and controlling the information of the laboratories, radiology stations, blood bank, and operating rooms, as well as exchange of data between NEHS and other (e.g. personnel management) information systems.

Installation of hospital information systems started in June 2008 in Kaunas University of Medicine Hospital, Klaipėda University Hospital and Vilnius University Hospital Santariškių Clinic. These systems are oriented towards improvement of healthcare services' quality as well as management of the healthcare institutions. The granted financial assistance for the project is LTL 15,195,000 (about EUR 4,400,776). The project is supported by the Republic

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of Lithuania – LTL 6,617,000 (about EUR 1,916,416) and partly financed by the European Union – LTL 8,578,000 (about EUR 2,484,361).

During this project, methodical recommendations and model documents will be prepared for all types of future NEHS users, including both – small healthcare entities not possessing their own information systems, but prepared to become direct NEHS clients, as well as large hospitals and other healthcare entities that seek to integrate their own information systems and enhance them with additional NEHS features. These methodical recommendations are essential for the successful functioning of NEHS as a system for the unified data collection and exchange for all Lithuanian healthcare institutions.

At the moment there is no legislation directly regulating implementation of eHealth strategy in Lithuania. In the frame of the project “eHealth services”, the existing legal acts of the Republic of Lithuania and the European Union are analysed and new documents that provide legal regulations for EHR data collection, use and exchange are being drafted (e.g. legal act for ePrescription services is being prepared). It must be pointed out that on 2 April 2008 the Minister of Health of the Republic of Lithuania adopted the ruling on Filling of Some Obligatory Records of Health Statistic Accounting and other Typical Forms in Healthcare Institutions Electronically. In the future, when EHR is fully implemented, healthcare institutions will be entitled to collect and keep data only electronically.

One of the major problems recognized in the process of implementation of the eHealth strategy is uncoordinated actions of healthcare institutions. Some of them do already possess own information systems. Therefore, it is hard to create an overall information system, which could process all different type of data.

However, initiatives of some healthcare institutions already showed good results, i.e. the possibility to register on-line for a visit to a primary or secondary level physician is already available in the Centro Polyclinics in Vilnius. Some electronic forms changed paper forms used in other healthcare institutions and according to the research carried out in Centro Polyclinics in Vilnius, the implementation of electronic forms instead of the ambulatory medical card (No. 025a/LK), has saved LTL 216,000 (about EUR 62,558) per year.

It should be noted that from the year 2006 the project “System of Patients Registration On-line” started in 20 hospitals and polyclinics in Lithuania. This project is financed from EU Structural Funds and is a part of eHealth strategy. While registration on-line does not work properly in all 20 aforementioned health care institutions, the phone line for registration to health care institutions is initiated. At the moment 6 health care institutions in Lithuania provide registration by phone line 1815. More information can be found at <http://www.sergu.lt/>.

The first pilot project of NEHS was executed in March 2007 in Širvintos primary healthcare centre. The new technologies automated various spheres of health care and enabled to make the first EHR. However, as National Audit Office of the Republic of Lithuania decided that Širvintos pilot project was not legal because no information system and data protection

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regulations were adopted by the Minister of Health of the Republic of Lithuania, it should be stated that eHealth strategy is not always implemented in a proper manner.

European Electronic Health Insurance Card (EHIC) was adopted in 2004 in Lithuania to ensure the need for health treatment of EU citizens being in other Member State. The State Patients' Fund also created database (EHIC Management System) for public use to check the validity of EHICs which were issued by the Territorial Patients' Funds of the Republic of Lithuania.

Digital Certificate Centre (SSC) was established in 2004 in Lithuania to provide E-commerce security solutions (software, hardware and certificates based on security to home and business users). Electronic signature is not widespread in Lithuania, because the system does not cover all territory of the Republic of Lithuania. However, there is already a possibility to send declarations signed electronically to the State Social Insurance Fund. According to the eHealth strategy, eSignature will be provided to all health care specialists, who will work with eHealth system, to ensure sufficient protection for operation of the system.

There is no Government health portal established yet. Though, there are other private health websites available, such as www.sveikata.lt, www.sveikas.lt, including links to health institutions, GPs, and health-related resources related to specialists as well as the society in general. Interactive communication with health institutions and health care specialists is in development stage. There is a possibility to provide specialists with the questions on some health websites (www.sveikata.lt, www.sveikas.lt), though there are no guarantees of receiving the answers.

One of eHealth services, which is now provided (from April 2007) in governmental level in Lithuania, gives a possibility to register via website of www.evaidzia.lt with person's bank account data (username, password) in this website and to get information about the provided medical services (registration data, inpatient, outpatient, sanatorium treatment) and prescribed medicines (only reimbursable). Regulatory framework for patients' summaries

One of the main directions in eHealth strategy is to create and develop EHR system. It is planned that at the beginning of the process the record will be comprised of a minimum set of patient data (essential information) and later the record will be supplemented with more detailed medical information which will be accessible for all users of the system. Meanwhile, some health care institutions have their local systems, where administrative data of the patients are already collected. The intention is to create the system, which integrates all local information systems to a single one.

The best example of local initiatives in EHR system is a project "Internet Patients' Record" initiated by Vilnius University Hospital Santariškių Clinics (more information on this project can be found at <https://viva.santa.lt/>). This is the only one hospital in Lithuania, which has such a system. Patients of this hospital after agreeing on conditions of the use of this system need to have mobile phone (for password when registering) and may get information via internet on descriptions of their laboratory research data, operation protocols, photos, images and other eClinical documents. It is planned to create special means letting patients to store

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personal information in EHR by themselves (i.e. body temperature, blood pressure, etc.). This system might be taken as an example to eHealth strategy executives regarding the product that should be created to cover all health care institutions in Lithuania.

Lithuania does not have specific legal provisions in the area of patients' summaries. However, as it was already mentioned, the Ministry of Health of the Republic of Lithuania is taking actions regarding EHR matters, i.e. the project "eHealth services" is implemented in three regional health care institutions. One of the aims of this project is to create health care record system. Thus, there is no legislation on patients' summaries at the moment, but practically EHR system is in the process of creation.

3.4 Regulatory framework for telemedicine

There are no specific legal provisions in Lithuania regarding telemedicine. Despite that, telemedicine services are introduced by the Telemedicine Centre of Kaunas University of Medicine (the Telemedicine Centre). The mission of the Telemedicine Centre is to initiate, form and introduce the politics of telemedicine development in the University and in the country and to prepare recommendations for health care institutions and governmental institutions. The vision which is behind the measures related to the development of infrastructure and conditions supporting eHealth, is undertaken by central and regional institutions and organizations in Lithuania focusing on bringing of comprehensive environment of services to citizens and patients. The support for health professionals who are able to provide high quality services to the society on the basis of evidence-based strategies is also key target of this vision. The Telemedicine Centre services cover the following fields: teleconsultations and second opinion services, distance education, image processing as well as information exchange and creation of international databases.

There are no legal regulations regarding the delivery of online medical consultations. However, the Minister of Health of the Republic of Lithuania adopted decision on Telephone Consultation by Health Care Providers (No. V-230, 14 April 2004). It regulates procedure and payment for telephone consultation services provided by physicians. Earlier telephone consultations were not regulated, although, it was a common practice to make a call directly to a physician for a long time. It must be pointed out that telephone consultations (Phone number 8 655 65 555) under the regulation adopted in 2004 are not so popular in the society because the patients are charged for them and the State Patients' Fund does not cover these expenses.

3.5 Regulatory framework for electronic prescriptions

There is no specific legal framework for electronic prescriptions. The working group is established at the Ministry of Health of the Republic of Lithuania to prepare provisions regarding ePrescription, however, no project of legal act is presented to the society yet. Generally, prescriptions are in paper form and are issued according to the decision on Prescription and Issue (Sell) of Medicines adopted by the Minister of Health of the Republic of Lithuania (No. 112, 8 March 2002). There is a provision regarding computerized handling

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of prescriptions of reimbursable medicines in pharmacies, but it is not the provision related to the ePrescribing system.

3.6 Overview of relevant legislation

There are several national legal regulations which deal with the overall development of the information society in Lithuania, many of which implicitly or explicitly are related to eHealth system.

Long-Term Development Strategy of the State (Government Decree No. IX-1187, 12 November 2002) and Long-Term Economic Development Strategy of the Republic of Lithuania until 2015 (Government Decree No 853, 12 June 2002). These strategies establish reform of the healthcare system which is to be based on the development of ICT systems.

National Concept of Development of Information Society (Government Decree No. 229, 28 February 2001) and National Strategy of Development of Information Society.(Government Decree No. 625, 8 June 2005) One of the main aims of these documents is to improve the quality of healthcare provision by using ICT, which is expected to facilitate accessibility to health information. There are also notions about the provision of information via Internet, preparation of legal basis for supply of information to patients via internet, and the introduction of electronic patients' card.

The eHealth Strategy for 2007 – 2015 adopted by the Minister of Health of the Republic of Lithuania (Regulation No. V-811, 9 October 2007) directly deals with eHealth services. The strategy is designed to restructure the whole system of healthcare, to modernize it, to make it function more effectively with the help of contemporary information and communication technologies. This report is generally based on the provisions of this Strategy. The goal to prepare long term eHealth Strategy was raised in the Decree of the Minister of Health of the Republic of Lithuania on the Development Program of the Information Health System (No. 387, 30 June 2002).

Position Paper on e-Government (Government Resolution No. 2115, 31 December 2002), the Law on Telecommunications (No. VIII-774, 9 June 1998) and the Law on Electronic Signature (No. 61-1827, 11 July 2000) are generally important for the development of electronic communications in Lithuania.

Further relevant legislation on the health care in Lithuania is the Law on Health System (No. I-552, 19 July 1994), the Law on Health Care Institutions (No. I-1367, 6 June 1996, last amended in 2007) and the Law on Medical Practice (No. IX-2148, 20 April 2004, last amended in 2007).

Protection of personal data is guaranteed in the Law on the Legal Protection of Personal Data (adopted on 11 June 1996, actual wording since 2004). The Law on Patients' Rights and Compensation for Health Damages (No. I-1562, 3 October 1996, last amended in 2005) is also relevant to eHealth.

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Insurance matters are regulated in the Law on State Social Insurance (No. IX-2535, 4 November 2004, last amended in 2007) and the Law on Health Insurance (No. IX-1219, 3 December 2002, last amended in 2007).

Description of Inter-schemes of Registers and Information Systems, which are assigned to the Ministry of Health (Resolution No. V-836, 16 October 2007) is very important for the National Electronic Health System (NEHS), while there is no other provisions on NEHS.

4 Regulatory framework for the healthcare profession

An overview of the regulatory framework for the medical profession in Lithuania is presented on the basis of the HiT country profile (2000) for Lithuania available at <http://www.euro.who.int/Document/E69920.pdf>, as well as the Law on Medical Practice (No. I-1555, 25 September 1996), the Resolution of the Minister of Health of the Republic of Lithuania Regarding the Regulations on the Medical Practice Licensing (No. V-396, 27 May 2004) and the Law on Health Care Institutions (No. I-1367, 6 June 1996).

4.1 Legal conditions for the practice of healthcare

The Law on Medical Practice establishes the conditions for medical practice in Lithuania for medical physician, resident physician, family physician and specialist physician. The general rule for all physicians wishing to gain professional qualification is medical university diploma. All medical professions are licensed in order to practice within a particular specialty and the license must be enrolled in the Register of Licenses of Healthcare and Pharmacy Specialists Practice (Register). License is issued according to professional qualification of the physician. Licensing is regulated by the Law on Medical Practice and by the Regulations on the Medical Practice Licensing, which implement 93/16/ECC Directive (as amended) and 2005/36/EB Directive regarding physician qualifications and recognition of qualification documents in Member States. Regulation of the Minister of Health of the Republic of Lithuania on approval of regulations governing recognition in the Republic of Lithuania of physician diplomas, certificates and other documents supporting official qualifications gained in the EU Member State, Switzerland or in a state-signatory of the Agreement on European Economic Area (No. V-43, 2 February 2004) supplement general legislation on recognition of qualifications.

The physicians are prepared at Vilnius University and Kaunas Medical University. The minimum duration of medical studies is six years (or minimum 240 credits). In order to be able to practice within a particular specialty, physicians have to continue studies in residency.

License is obligatory for physicians intending to practice medicine. The State Accreditation Office for Healthcare Practice (the Department of the Ministry of Health) issues licenses for physicians and registers them with the Register. License Register contains data on the issuance, re-registration, suspension of and revocation of licenses. License is of indefinite duration, if all requirements contained in the Regulations on the Medical Practice Licensing are fulfilled.

Physician is described in the Law on Medical Practice as medical physician, resident physician, family physician and specialist physician, who has medical qualification and license to act within a particular specialty. The main rights of the physician established in the Law on Medical Practice are as follows:

- 1) to issue prescriptions;
- 2) to certify a person's birth and date facts;

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-
- 3) to issue personal health certificates;
 - 4) to refuse to apply individual health care services, which contradict the ethics principles of the physician and may cause real danger to the life of patients or physicians, except when urgent medical help is given;
 - 5) to participate in activity of physicians' professional union;
 - 6) other rights.

The Law on Medical Practice also regulates duties, liability and control of medical practice providers.

The Minister of Health of the Republic of Lithuania adopts medical norms for licensed practices. Thus, specifications for particular medical professions (rights, obligations and acts, which can be performed) can be found in such medical norms that are considered as the main document which must be observed by health care professionals.

Professional qualification of nurses is determined in the Law on Nursing Practice (No. IX-413, 28 June 2001). Nurses, as well as physicians, have to obtain university diploma and license to practice as a nurse. Radiologists do not need license, but professional qualification is obligatory.

In addition, the Law on Medical Practice sets forth the conditions for physicians of EU Member States to obtain the right to practice temporally or to give one-off medical practice service in Lithuania. Physicians from other EU Member States may temporally act in Lithuania without a license, though they have to inform the Ministry of Health of the Republic of Lithuania about their medical practice before starting it. However, for permanent medical practice they have to obtain the license according to the same rules applicable to the Lithuanian physicians.

4.2 Control over the practice of medicine

The Ministry of Health and its authorised institutions control the professional activities of physicians. The professional competence of physicians is assessed by the commission for the assessment of professional competence of physicians who are engaged in a respective type (speciality) of professional medical practice (the "Assessment Commission"). The Assessment commission qualifies professional knowledge and practice in comparison to documents, which prove qualification of physicians (university diplomas, licences, certificates). The Assessment commission may adopt decisions stipulating that qualification of the health care professionals does not conform to licence requirements, or that drawbacks of the activities of the physicians should be considered as rough practice mistake or often repeated practice mistakes, or that health care professional can not perform professional obligations because of his/her state of health.

The State Health Care Accreditation Agency under the Ministry of Health (the State Health Care Accreditation Agency) controls medicine practice of license holders and the compliance of conditions of the licensed activities. The State Health Care Accreditation Agency is entitled to suspend and revoke the license of the health care professionals in Lithuania.

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The license might be suspended or revoked on the initiative of the State Health Care Accreditation Agency or at the request of the Ministry of Health of the Republic of Lithuania, the Lithuanian Bioethics Committee, the Medical Audit Inspectorate under the Ministry of Health, the State Patients' Compensation Fund under the Ministry of Health, regional physician, municipal physician, founders of personal healthcare institutions or the administrators of their authorized organizations, head of personal healthcare institution, respective professional organizations of physicians, organizations protecting patients' rights, by providing to the State Health Care Accreditation Agency a motivated request and research or other documents with a finding or findings evidencing the reasons which might result in the suspension or revocation of the license.

The Medical Audit Inspectorate under the Ministry of Health of the Republic of Lithuania exercises state control and expert examination over the quality of services provided by legal and natural persons engaged in personal health care activities.

Medicine Ethic Commissions in the healthcare institutions control how specialists of medical practice comply with the medicine ethic requirements. These commissions are formed according to the standard regulations prepared by the Ministry of Health of the Republic of Lithuania.

The Lithuanian Physicians' Association adopted the Code of Ethics, which determines the obligation of the Lithuanian Physicians' Association to observe compliance by the physicians with the principles of professional ethics and the Code of Ethics. Cases regarding violations of the professional ethics by physicians are solved by the Ethic Commission, which may decide to revoke the membership of the physician in the Lithuanian Physicians' Association.

However, physician's revocation from the Lithuanian Physicians' Association itself does not have a direct impact on revocation of license of medical practice. Still such information could be provided to the State Health Care Accreditation Agency, which is entitled to commence the investigation regarding the suspension or revocation of the medical practice license.

When particular regulation regarding physicians' actions in medical practice is not provided in legislation and/or in the Code of Ethics, physicians have to obey common ethic and moral principals, which are formed in the physicians' everyday practice.

It must be pointed out that the Code of Ethics does not mention anything about eHealth services.

4.3 Professional liability

Physicians' professional liability is regulated by the Civil Code of the Republic of Lithuania (the "Civil Code") and the Law on the Rights of Patients and Compensation of the Damage to their Health. The amendments to the latter law came into effect in 2005 and determined functional mechanism for the regulation of the compensation of the damage to patients' health. The law stipulates the requirement for health care institutions to insure their civil liability for damage to patients' health (minimum insurance sum LTL 50,000 (about EUR 14,481)). However, this order of compensation practically functions insufficiently, because courts are overloaded with claims, procedure is long, difficult and expensive. Therefore, the new draft law is currently being prepared and it is planned to establish the Ombudsmen of Patients' Rights, which would examine complaints on violations of patients'

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rights. It is believed that the Ombudsmen of Patients' Rights would reduce judicial proceedings. However, the Ombudsmen should not examine the requirements for damage, and thus it is hard to believe that the goal to secure efficient compensation of damage to patients' health will be achieved. The draft law also changes obligatory amounts of civil liability insurance, which should depend on annual turnover of the health care institution. Compensation system of damage to patients' health in Lithuania is based on tort law, which requires proving the existence of physicians' illegal actions, damage, a fault committed by physician and the causality of the illegal actions and the caused damage. It must be noted that the presumption of fault in Lithuania. The liability of health care professionals might be reduced when the behaviour of the patient also threatens to impair his/her health (e.g. when the patient violates obligations he/she has to obey).

The Lithuanian Physicians' Association has prepared a suggestion to the Parliament of the Republic of Lithuania inviting to introduce the concept of strict liability of health care providers (i.e. faultless liability) in the Lithuanian health sector. However, the new draft Law on the Rights of Patients and Compensation of the Damage to their Health does not include such changes.

Professional liability is also regulated under criminal and administrative law in the Republic of Lithuania.

Criminal liability is applied according to general rules established in the Criminal Code of the Republic of Lithuania (the "Criminal Code"). The Criminal Code establishes criminal liability for unlawful termination of pregnancy, performance of forbidden biomedical research with human-beings and embryos of human-beings, etc.

Administrative liability of health care professionals is established for failure to perform or improper performance of the duties, which are established in the laws and other legal acts of the Republic of Lithuania.

4.4 Professional secrecy

The general constitutional principle "The private life of a human being shall be inviolable" is elaborated in the Civil Code and the Law on the Rights of Patients and Compensation of the Damage to their Health.

Publicity of information regarding patients' health is limited in order to ensure inviolability of secrecy of person's private life and state of his/her health. The Law on Health Care Institutions establishes obligation of a health care institution to protect patients' medical confidentiality, except for the cases where a health care institution must provide information about a patient or where a patient gives his/her consent to make the information concerning the state of his/her health public.

According to Resolution of the Minister of Health of the Republic of Lithuania on Criteria of Secrecy of Person's Health, all information about the state of a person's health, diagnosis, prognosis and treatment, as well as any other information about patient is considered confidential even after the death of the patient. The employees of health care institutions have a duty not to disclose this information, which is gained when executing professional obligations, without consent of the patient or his/her representative. Exceptions are applied

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when information is submitted to the health care specialists, who treat, examine, nurse and register patients and only when it is guided by the interests of a patient, also to the court and other official institutions, which have a right to require such information as well as to the representatives of the patient when he/she is unconscious and it is guided by the interests of a patient.

Health care professionals are obliged to act according to the principals of confidentiality and deliberation. Confidentiality means that information may not be disclosed at any stage of examination, treatment of the patient, in biomedicine research, education process and in administration of medical documents. Health care professional has to be deliberate and to ascertain whether the patient understands the consequences of the consent to disclose information, when he/she agrees to give permission.

When medical secrecy is illegally disclosed, compensation for pecuniary and non-pecuniary damage can be adjudicated. Criminal liability for illegal collection, disclosure and use of confidential information is also established in the Criminal Code.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

The principal legal act that transposes the provisions of Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (the Directive) into the Lithuanian national law is the Law on Legal Protection of Personal Data (No. I-1374, 11 June 1996) (the Law).

In addition to the Law, several secondary normative legal acts establish detailed rules and obligations of the parties concerned, as regards, for instance, the notification procedure, organization and scope of responsibilities of the supervising state institutions, etc.

Among the most important secondary normative legal acts are the Resolutions of the Government of the Republic of Lithuania Concerning the Reorganisation of the State Register of Personal Data Controllers, the Approval of the Regulations of this Register and of the Procedure for Notification by Personal Data Controllers of Automated Processing of Personal Data (the Rules on Notification) and Concerning the Setting up of the State Data Protection Inspectorate (SDPI).

Furthermore, the Orders of the SDPI On Approval of the Rules on Carrying out of the Prior Checking, On Recommended Form of Notification of Data Processing, On the Requirements for the Description of Data Protection Measures and the Description of Data Protection Measures, which supplement the laws with necessary technical and procedural details, must be mentioned.

Generally, the provisions of the Law and the secondary legislative acts follow the lines of the Directive. Lithuanian national legal acts operate with the same terminology, concepts, principles and rules.

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

Regulation of processing of “special categories of personal data” in the sense of Article 8 of the Directive has been implemented into Lithuanian national law by the following provisions. The Law differentiates between the concepts of “personal data” and “special categories of personal data”. The former is defined in Article 2(1) of the Law as “any information related to a natural person, the data subject, who is identified or who can be identified directly or indirectly by reference to such data as a personal identification number or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity”. Article 2(8) of the Law defines “special categories of personal data” as:

- Data revealing racial or ethnic origin of a natural person;
- Data revealing political opinions or religious, philosophical or other beliefs of a natural person;
- Data concerning membership in a trade union;
- Data concerning health, sexual life and criminal convictions.

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Article 5(2) of the Law establishes the criteria for lawfulness of processing special categories of personal data. Accordingly, it is prohibited to process special categories of personal data, except in the following cases:

- The data subject has given his/her consent;
- Such processing is necessary for the exercise of the rights and discharge of obligations of the data controller, as part of his/her employment or civil service, in the field of labour law in the cases laid down in laws;
- It is necessary to protect essential interests of the data subject or of any other person, where the data subject is unable to give his/her consent due to a physical disability or legal incapacity;
- Processing of personal data is carried out for political, philosophical, religious or trade-union purposes by a foundation, association or any other non-profit organisation, as part of its activities, on condition that the personal data processed relate solely to the members of such foundation, association or organisation or to other persons who regularly participate in such foundation, association or organisation in connection with its purposes. This category of personal data may not be disclosed to a third party without the data subject's consent;
- The data have been made public by the data subject;
- The data are necessary, in the cases laid down in laws, for the prevention and investigation of criminal or other illegal activity;
- The data are necessary for legal proceedings;
- It is a legal obligation of the data controller under laws to process such data.

Additionally, the Law establishes that data about a person's health may also be processed for the purposes and in the manner laid down in the Law and other laws pertaining to health care. The provisions of the Law shall be discussed in point 0 below.

Furthermore, the Law contains rules that regulate the use of personal identification number. In particular, the first part of this Article defines personal identification number as a "unique sequence of digits assigned to a person in the manner laid down in the Law on the Residents' Register".

The Law provides that it is permitted to use personal identification number when processing personal data only with the consent of the data subject, except in certain cases specified in the Law. The said exemptions include the use of the personal identification number by legal persons involved in activities related to health care and social insurance as well as in the activities of other social care institutions. Legal persons subject to this exemption may use personal identification number only for the purposes for which it has been disclosed and only in the cases where a legitimate and defined purpose of personal data processing cannot be achieved without the personal identification number concerned.

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5.3 Information and access rights of data subjects

In accordance with the Law, data subjects have the right to obtain all information about them, which is being processed by a data controller. In particular, the Law obliges the data controller or the data processor to communicate the following information to a data subject, who has submitted proper identification documents:

- The source of personal data that has been collected;
- The type of personal data that has been collected;
- The purposes for which the personal data are processed;
- The data recipients to whom the data are to be or have been disclosed at least during the last year.

In accordance with the Law, having received an enquiry from the data subject concerning the processing of his/her personal data, the data controller must provide information as to whether personal data relating to the data subject are processed and disclose to the data subject the requested data no later than within thirty calendar days of the date of approach by the data subject. If the data subject so requests, the information must be provided in writing. Once per calendar year the data controller must provide such information to the data subject free of charge. When such information is disclosed for a fee, the amount of the fee shall not exceed the cost of disclosure of the data.

Furthermore, the Law establishes the procedure, whereby a data subject may receive assistance of the SDPI in exercising his or her information and access rights. Article 29(2) of the Law provides that data subjects are entitled to approach the SDPI with requests to collect from registered data controllers data subject's personal data or information on the processing of his or her personal data and to make the collected data or information available to him/her.

If the data subject approaches the SDPI in person, he or she must provide a document certifying identity of the data subject. If a data subject approaches the SDPI using electronic means, his or her request must be signed with an electronic signature. In this case the reply to such a request is sent by electronic mail or, if the data subject requests so, by post or shall be hand-delivered at the address specified in the request. The reply sent by electronic mail is signed with an electronic signature of the head of the institution or a person authorised by him.

In accordance with the Law, when providing the assistance described above, the SDPI does not have the right to collect data which constitutes classified information as defined in the Law on State and Official Secrets. The assistance of the SDPI is subject to a levy of the size determined by the Government.

The Law also establishes that data controllers registered in the State Register of Personal Data Controllers, having received from the SDPI an inquiry about the implementation of the right of a particular data subject to have access to his/her personal data, no later than within fifteen calendar days, shall give a reply to the SDPI in the manner established by the latter (specifying in the reply the personal data requested by the data subject or giving information about processing of his/her personal data, or indicating that personal data of that particular data subject is not processed by the data controller concerned). Data controllers must ensure

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security and confidentiality of data subjects' personal data received by or disclosed to the SDPI.

5.4 Other relevant rules regarding personal data protection

The Law provides special rules that regulate processing of personal data for the health care purposes. It establishes that personal data on a person's health (its state, diagnosis, prognosis, treatment, etc.) may be processed by an authorised health care professional. A person's health shall be subject to professional secrecy under the Civil Code, laws regulating patients' rights and other legal acts.

Article 10(2) of the Law provides that processing of personal data for scientific medical research purposes must be carried out in accordance with the Law and other laws.

Article 10(3) of the Law provides that personal data on a person's health (also for scientific medical research purposes) may be processed by automatic means only having submitted a corresponding notification to the SDPI. In this case the SDPI must carry out prior checking.

The unlawful personal data processing is subject to administrative liability. In accordance with the Code of Administrative Violations of the Republic of Lithuania, the administrative sanctions in the form of fines can amount up to LTL 1,000 (EUR 290) for each instance of violation. In case of repeated violation, the fines could reach LTL 2,000 (EUR 580) for each instance of violation. In addition, a natural person is entitled to an adequate compensation if a breach of the Law has resulted in loss or damages to that person. The amount of the compensation is determined on a case-by-case basis.

6 Rights and duties of healthcare providers and patients

The main legal act, which regulates the rights and the duties of patients is the Law on Patients' Rights and Compensation for Health Damages (No I-1562, 3 October, 1996, last amended in 2005). Despite this legal act, Civil Code likewise regulates the rights and the duties of the patients, when health care services are provided according to the contracts for personal healthcare services (i.e. when State Patients' Fund does not cover the expenses for the health care services).

The rights and the duties of healthcare providers are regulated in the Law on Medical Practice (No IX-2148, 20 April 2004, last amended in 2007).

There is also other relevant legislation in this matter (e.g. the Law on Health System, the Law on Health Care Institutions), however this chapter is based on provisions from the Law on Patients' Rights and Compensation for Health Damages, while it is special legal act in accordance with common legislation.

6.1 Scope of the law

The purpose of the Law on the Patients' Rights and Compensation for Health Damages is to regulate the rights of the patients and the procedure for implementation of those rights. This Law is applied to health care services, expenses whereof are covered both from the budget of mandatory health insurance fund and from patient's finances.

According to this law a patient is "a person who uses the services provided by health care institutions regardless of whether he/she is healthy or ill, and while receiving these services has rights and obligations established under the laws".

Quality health care means "health care, which is provided according to the health care norms and other legislation, and is executed by the individuals, who are licensed to engage in medical or other particular practice in the health care institutions, which have licences to provide health care services and have insured their civil liability for the damage to the patients".

Health care services (according to the Law on Health Care Institutions) are the result of activity based upon an agreement between an institution and patient (in the Law on Health Care Institutions the term of "the client" is used). The patients of services may be the patients of the LNHS activities stipulated in the Law on the Health System as well as other companies and individuals.

6.2 Duty of the patient to co-operate

The duties of the patients are not regulated as rightly as their rights in Lithuanian legislation. Even though the Law on the Patients' Rights and Compensation for Health Damages does not mention patient's duty to co-operate, Civil Code establishes a provision on co-operation, which states that the patient should give to the provider of personal healthcare services all possible information and assistance, which may be reasonably required for the performance of the contract. In addition, the new project law amending the Law on the Patients' Rights and

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Compensation for Health Damages includes the list of the patients' duties and one of these duties is to co-operate with specialists and other employees of the health care institution.

6.3 Right to quality care

According to provisions of the Law on the Patients' Rights and Compensation for Health Damages, qualified health care has to be provided to every patient. The rights of patients may not be restricted in health care institutions because of patients' gender, age, race, nationality, language, origin, social status, faith, beliefs, sexual orientation, genetic features, disability or other unreasonable criteria. The other conditions for qualified health care are: (a) respect to the patient's personal privacy; (b) execution of any professional activities following the professional obligations and standards; (c) thorough and reasonable explanation to the patient about every action performed by the health care specialist; (d) rendering of means of anaesthesia to the patients in order to reduce the suffering which was resulted by health disorders; (e) prohibition to use the patient's body and the parts of his/her body for commercial benefit.

6.4 Right to free choice

According to the Law on the Patients' Rights and Compensation for Health Damages, a patient has the right to select a physician, nursing staff member and health care institution. This right may be limited only in accordance with the procedure established by the laws of the Republic of Lithuania.

6.5 Rights related to information about the state of health

The patient has the right to information on the state of his/her health, diagnosis of the disease, results of medical examination, methods and prognosis of the treatment. When providing information about the treatment, the physician must explain to the patient the course of the treatment, possible results of the treatment, possible alternative methods of the treatment and other circumstances, which may have an effect upon the patient's decision to refuse the proposed treatment, as well as the outcomes of the refused treatment. The information must be provided to the patient in a form comprehensible to him/her with an explanation of the special medical terms involved, taking into consideration his/her age and state of health. In addition, a patient has the right to hear the other specialist's opinion about the condition of the patient's health and the proposed treatment.

Health care institution may not provide above mentioned information to the patient, including minors from 16 to 18 years old, only in cases when this information could be a ground for damage for a patient to occur (would harm the health of the patient or would cause a danger to his/her life). In such cases all information has to be provided to the representatives of the patient and this is recognised as provision of information to the patient. Information, which

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has been given to the representative, must be provided to the patient immediately after the danger, which may cause the above mentioned harm, disappears.

In addition, a patient has the right not to know. The information can not be provided to the patient against his/her will, however, his/her will must be clearly expressed in the contract on provision of health care services and confirmed by patient's signature in his/her medical documents. This rule is not applied when non-provision of information could result in harmful outcomes and it is impossible to avoid such outcome in any other way. The fact that the patient was informed against his/her will has to be indicated in the patient's medical documents.

6.6 Right to give consent

Patients, including minors from 16 to 18 years old, may be treated or other health care or nursing services may be provided only with the consent of the patients. Health care and nursing services are provided to the minors of up to 16 years old only when the consent of their representatives is given, except the cases when such consent would infringe interests of the minor patient. A patient has the right to know about possibility to select method of diagnostics and treatment (if there is such possibility according to the health care norms) and he/she should be allowed to choose one of them. The Law on the Patients' Rights and Compensation for Health Damages also establishes cases (e.g. emergency health care) when the consent of the representatives is sufficient to provide health care services.

The form of the consent is not stipulated in the Law on the Patients' Rights and Compensation for Health Damages, thus, the patient may give his/her consent orally, in written or it can be implied from the actions of the patient, except the particular cases, which are established in the legislation and require written form of consent (e.g. written consent is mandatory for medical intervention).

A patient can also recall his/her consent for treatment at any time. The will of the patient, previously expressed in written, is taken into consideration (in such scope that the bigger harm would be avoided) when a patient is incapable to express his/her will for treatment, diagnostics and method for treatment because of his/her state of health. Treatment is provided without the consent of the patient only in cases of real threat to the health and life of the patient or people surrounding him/her.

6.7 Rights related to the patient's medical record

The Law on Health Care Institutions states that every patient's case history, nursing record or out-patient card has to be managed. The originals of these documents have to be kept at the institution, meaning that medical documents of the patient are the property of the health care institution. Despite that, if the patient so desires, he/she must be provided with the history of his/her illness or other medical documents about him/her, except the cases if this could have a basic effect to the patient's health and even endanger his/her life (this has to be decided by the physician treating him/her, or a physicians' consultation). In such instances the treating physician has to make relevant notes in the disease case history.

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The patient shall have the right to request that copies of the case history of his diseases and (or) of other documents which are made at his expense. This right of the patient may only be limited following the procedure established by the laws of the Republic of Lithuania. The physician must explain the significance of the notes made in the case history of the patient's illnesses. If the patient's request is reasonable, the physician must correct, complete, remove, explain and (or) change inaccurate, incomplete, ambiguous data or data not related to the diagnosis, treatment or nursing. If the treating physician fails to satisfy such patient's request, the consultation of physicians will then decide the reasonableness of the patient's request.

6.8 Right to protection of privacy and intimacy

Accessibility of information related to individual health is restricted in order to ensure the inviolability of privacy and the person's health secret. Patients have the right to confidentiality of information about their state of health. Right to the protection of privacy is generally related to administration of the information about a patient and his state of health, providing information about the patient to the third parties and administration of information about the patient after his/her death.

6.9 Right to representation in case of incompetence

According to the Law on the Patients' Rights and Compensation for Health Damages, representative of the patient is either a legal representative (parents, adoptive parents, guardians, custodians) or a designated representative, which is selected by the patient. Minors of the age up to 16 years are represented in every occasion, except when it contradicts the interests of the minor patient. Minors of the age from 16 to 18 years are treated as every other patient and may exercise their rights themselves, however, legal acts expressly state when representation is mandatory.

Representatives may also represent adult patients when the latter are not capable to do it themselves. Representative exercises the rights of the patient when urgent healthcare services have to be provided to the patient and patient is not able to express his will because of the age or his/her state of health.

7 Identity management in the health sector

This chapter mostly is based on information from IDABC-report “eID Interoperability for PEGS. Lithuania” [RD9].

7.1 Overview

None of the eIDM systems operating in Lithuania constitute a uniform user authentication mechanism for all eGovernment services, i.e. services related to the telecommunications, information technologies, which convert delivery of public services into digital technologies. However, the majority of the eIDM systems of the public sector in Lithuania rely on authentication systems of the private sector, namely on eBanking authentication means. The portal Government Electronic Gates (the “Portal”) is the front-office application intended for access to eGovernment services. At present, however, the number of eGovernment services available in the portal is limited. One of the eGovernment services is the possibility to check the medical services rendered and the medicaments prescribed.

eBanking authentication means are used upon agreement between a person and commercial bank and form the basis for user authentication both in the Portal and in other separate eGovernment applications, providing interactive services independently from the Portal. Other eIDM systems are based on personal certificates, issued by qualified certification service providers, or usernames and passwords.

As regards future plans concerning eIDM systems, the eID card will be introduced in Lithuanian market from 1 January 2009 (see 7.6).

Other initiatives include SIM cards of mobile phones containing PKI certificates. For example, mobile phone can be used by patients to access their EHR in Vilnius University Hospital Santariškių Clinics.

Authentication information of natural persons is stored in the Residents’ Register of the Republic of Lithuania (the “Residents’ Register”). The personal code is considered as the main identifier of a natural person. The use of the personal code granted by the Residents’ Register is forbidden, except when the data subject allows such use. The other exception from the abovementioned rule includes the use of the personal code without the consent of the person for purposes of state registers and management of information systems under provisions established in legal acts.

Under the Law on Electronic Signature, the eSignature has the same power as the signature of the authorized representative of the legal person confirmed with the seal of the legal person in written document.

It should be noted that the year 2004 saw the establishment of the Digital Certification Center, which deals with issuing of certificates for eSignature. However, authentication of legal persons is not available in all eGovernment applications, therefore eSignature is not so popular in the society. Relatively high prices of the certificates are also one of the reasons of

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low usage of eSignature. There is a goal to improve all government services in a couple of years in order to use eSignature overall. Such plan should raise the popularity of eSignature.

The main legal acts concerning the e-IDM systems are the Law on Identity Cards, Law on Passport, Law on Electronic Signature, Law on State Registers, Law on Legal Protection of Personal Data, and Resolution on Position Paper on eGovernment.

7.2 Social security card

There are no changes in social insurance system regarding electronic social security cards. Laminated paper forms are used for social insurance certificates, which can not be used for electronic ID management. However, social insurance number is used in electronic database SVEIDRA, managed by the State Patients' Fund. Social insurance number helps to find out whether a patient has obligatory health insurance and whether the State Patients' Fund covers expenses of patient's treatment. More about SVEIDRA is in section 7.3.

7.3 Patients identifier

SVEIDRA is an information management system for the public healthcare service. The system is used for the management, storing, exchanging, analysing and reporting of all the services provided by healthcare institutions. SVEIDRA is a specialized accounting system for the state funds, allocated to reimburse for healthcare services provided by healthcare institutions. The system was designed and developed for the State Patients' Fund of the Republic of Lithuania. SVEIDRA is composed of different sub-systems, e.g. registry of services covered by the state health insurance system; registry of initial health screening reports for insured persons; registry of issued state health insurance system certificates; European Health Insurance Card administration and issuing subsystem, etc.

When a patient comes to the health care institution, the social security number helps to find information in SVEIDRA system and to detect whether the person is insured with the health insurance. At the moment there are no health insurance certificates (except EHIC, which are not numerous, since they are possessed only by people who travel to other EU Member States to work or to study). Thus, the State Patients' Fund cooperates with the State Social Insurance Fund, which provides necessary information about patients' social insurance. Patients have to submit passport, ID card or other personal document containing photo and code to the health care institution and only thereafter the health care services can be provided. Otherwise, the State Patients' Fund will not cover health care expenses for the person, who is not insured, except urgent aid.

SVEIDRA is the biggest solid distributed information system in Lithuania, covering the entire territory of the country and having around 5000 users working with the system at the moment.

7.4 Authentication of healthcare professionals

As it was already mentioned, the State Health Care Accreditation Agency is responsible for licensing practice of state health care professionals. Limited information about issued or cancelled licences can be found on the official site of this agency <http://www.vaspvt.gov.lt/>

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and on the webpage of the State Public Health Service under the Ministry of Health:
http://www.vvspt.lt/licencijos_leidimai.php?p=ll_licencijos

Licenses of health care professionals are registered in the Register of Licenses of Health Care and Pharmacy Specialists' Activities. The information which is publicly announced to the society comprises the following: the name and surname of the practitioner, type of professional qualification, name and registration number of the license and date of its issuance.

At present, the Ministry of Health of the Republic of Lithuania in cooperation with the State Patients' Fund are establishing electronic administration system of medicine development METAS, which is designed for health care institutions, all health care professionals and their associations, and official institutions issuing licences. This pilot project is not registered so far, however, its goal is to collect all information about the activities of health care professionals and help them to plan development of professional qualification. This project should improve communication between official institutions and health care professionals regarding the health care professionals' qualification development.

7.5 Exchange of health-related data

A specialized internet portal for patients, physicians and eHealth is planned to be developed during the first stage of eHealth Strategy and possibility to use this portal interactively (to get answers, consultations, to participate in discussions and preparation of the projects) will be provided in the second stage. At present, there are no official internet portals established by the government, though there are some private initiatives (e.g. www.sveikata.lt, www.sveikas.lt). No legislation regulating the exchange of the health-related data in internet portals is prepared in Lithuania.

7.6 The ID-Card

The main identity documents issued in Lithuania are passports and identity cards for citizens of the Republic of Lithuania (the citizens) and residence permits (temporary and permanent) for non-citizens of the Republic of Lithuania (non-citizens). The passport was the principal identity document of citizens until 2001 when personal identity cards became the obligatory personal document instead (only as regards the issuance of a new identity document). Currently, personal identity cards are issued to persons aged 16 and above, and the passport may be issued on additional request and is mainly intended for entry to countries that maintain a visa regime for Lithuanian citizens. Due to this shift, some citizens possess both a passport and a personal identity card, others - either a passport or an identity card.

The passport contains data printed on it, namely, the name(s), surname(s), gender, date of birth, place of birth, personal code, citizenship, picture, signature of the bearer, date of issuance, the issuing institution, period of validity, passport number. The validity of the passport is 10 years after its issuance.

The personal identity card contains first name(s), surnames, gender, date of birth, personal code, citizenship, picture, signature of the bearer, date of issuance, institution of issuance,

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period of validity, card number. Personal identity cards are issued for a period of 10 years. The identity cards are of ID1 format under ICAO Doc. 9303 standard (ISO 7810).

It should be noted that at present electronic eIDs do not exist in Lithuania. The current ID cards only contain visual information and do not possess a chip for storing information. However, Law on Identity Cards and Passport Law were amended and new provisions regarding eID will come into force on 1 January 2009. It is planned that multifunctional eID cards could be used as a means to access and receive public services by electronic means both in the Republic of Lithuania and the rest of Europe. Moreover, it is anticipated that the eID card would be used for both state and local eGovernment services and private applications. eID card will have two independent chips (microprocessors). The first one – contact chip – would enable to install and maintain a few applications and would have the functionality of an eSignature designated to authenticate the users of eGovernment services and to sign electronic documents. The second one – non contact chip – would also enable to install and maintain a few applications, and could ensure the identification of persons and functionality necessary for travel documents as well as the use of eID in applications of additional services (e.g. eTickets, loyalty programmes, entrance control and etc.).

It is anticipated that the eID card could be used in future in eHealth applications (e.g. ePrescription, ePatient's card).

8 Electronic prescription

Decree of the Minister of Health of the Republic of Lithuania on Prescription and Dispensing (Selling) of Medicines (No. 112, 8 March 2002) establishes the rules for filling prescriptions for medicinal products and for dispensing (selling) medicinal products to the general public. This decree does not regulate ePrescription. Therefore, the procedure on preparation of the draft law on ePrescription has already been initiated.

There are three forms of prescriptions: for medicines, for drugs and for reimbursable medicines. Two latter have mandatory form and the first one may even be printed with the computer. Despite filling differences, all prescriptions have to be filled by the physicians themselves. The physician has to indicate the name, surname of the patient, date of birth, address, number of the patient's record, date of dispense and physician's phone number. The prescription has to be clearly written in Lithuanian, signed and confirmed with the personal seal of the physician. It is forbidden to correct and to make amendments in the prescriptions. There can not be any records, marks and other graphical signs on the other side of the prescription form.

Prescriptions of reimbursable medicines differ from the other prescriptions, because they are controlled by the State Patients' Fund, which issues passport of the reimbursable medicines to every person. The passport contains the sticker for identification of the physician (with physician's barcode) for assuring better control of dispensing reimbursable medicine prescriptions and selling thereof.

It should be stated that the commerce names of the medicines have to be accurately indicated in the prescription. If commerce names of medicines of different manufacturers are the same, the physician should also indicate the name of the manufacturer of the medicine.

9 General assessment

As you can see from the all above mentioned, Lithuania is trying to create eHealth system that could correspond to the demands of patients, physicians and other participants of the health care system in the most appropriate way. The best initiative that has been made in eHealth development in Lithuania is the creation of the eHealth Strategy for 2007 – 2015.

Implementation of some of the projects foreseen in the eHealth Strategy is already in progress (e.g. System of On-line Registration of the Patients) and some pilot projects have already been executed (pilot project in three health institutions in Vilnius, Kaunas, Klaipeda on the creation of the EHR system). The Ministry of Health is working on preparation of the required draft laws on eHealth and coordinates actions regarding implementation of the new projects.

However, it must be mentioned, that neither system has been perfected yet. Majority of the health care institutions have their own information systems which are difficult to unite to the national one. Furthermore, as regulatory framework is not duly prepared, practical problems arise in the execution of the new projects (the decision of National Audit Office as of 17 March 2008).

The most important thing in the field of eHealth is that the improvement on eHealth can be already seen. Ministry of Health is reporting on every new action taken regarding electronic achievements. It is believed that patients, physicians and other participants of health care system will feel the results of the execution of the eHealth Strategy in Lithuania in the nearest future. Nevertheless, a lot still is to be done.

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