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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE LATVIA

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European Commission
Directorate General Information Society

Brussels

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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/20080702-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/eeurope/i2010/docs/benchmarking/

	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

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

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

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OCSP ..... Online Certificate Status Protocol

PKI..... Public Key Infrastructure

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NRN..... National Register Number

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

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SSCD ..... Secure Signature Creation Device

SSIN..... Social Security Identification Number

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TTP ..... Trusted Third Party

3 Introduction

3.1 General overview of the Latvian healthcare system

A comprehensive and recently updated (2008) overview of the Latvian healthcare system can be found in the Latvian HiT country report published by the European Observatory on Health Systems and Policies (written by Ellie Tragakes, Girts Brigis, Jautrite Karaskevica, Aiga Rurane, Artis Stuburs and Evita Zusmane and edited by Olga Avdeeva and Marco Schäfer)
http://www.euro.who.int/Document/E91375.pdf.

From the executive summary of this report, we reproduce the following important observations:

"The Latvian health care system has undergone a remarkable transformation in the years since independence, and is now in the process of consolidating its new structures and institutional arrangements. Having abolished the highly centralized system that prevailed during the Soviet period, it has focused on decentralization of health care delivery, administration and financing; full or partial privatization of some kinds of provider institutions; and the establishment of independent primary care practices, which have led to a wide variety of legal forms of health care providers and institutions. It has experimented extensively with a variety of social insurance structures ranging from highly decentralized to partially recentralized arrangements, as well as with organizational forms of health care delivery in parallel with reforms of the state administrative system. The wide-ranging reforms and continuous and ongoing process of change are prompted by the perceived need to increase the efficiency of health care financing and provision and to improve the quality of care."

"Latvia is in the unique position of possessing a tax-funded "social insurance" system with a purchaser–provider split. The central Government is responsible for financing the statutory health care system through tax revenue. In addition, financing for health services comes directly from household payments as well as VHI. Tax revenue allocated for health care by the Ministry of Finance is transferred (via the Treasury) to the Health Compulsory Insurance State Agency (HCISA), a state-run organization under the jurisdiction of the Ministry of Health, which signs contracts with all statutory health care providers. What differentiates the Latvian financing system from most general tax-based systems is that the funds from the central government budget are transferred to the HCISA, which – together with its five regional branches – acts as purchaser of health services on behalf of the entire population."

"Payment methods for services and health care professionals have evolved over several years and are quite complex. They are determined by government regulations and defined in contracts. Health care personnel working as employees in health care institutions are salaried. GPs are paid through capitation, plus fees for defined activities, bonus payments and fixed

allowances (such as a practice allowance). In addition, they hold funds for the purchase of certain secondary care services. Specialists are paid by means of fees for flat rate episodes of illness. Hospitals are remunerated by a per diem fee with additional activity-based payments."

"After the re-establishment of independence in 1990, numerous changes were introduced in Latvia, including a transition to a market-based economy, privatization, the development of entrepreneurship, and a new approach to social insurance. These developments formed the background for the initial reforms in the health system, focusing on decentralization, attempting to diminish the role of the State and replacing it with market-driven incentives. Throughout the 1990s, a major focus of reforms was on the development of the "social insurance" structure of financing, which underwent numerous transformations, and the introduction of a PHC system. In 1998 the SCHIA founded the Primary Health Care Support Fund, which, together with international assistance organizations, funded retraining of physicians as GPs and provided assistance for setting up PHC practices. Every inhabitant of Latvia was to register with a family physician.

In the area of reimbursement systems for health care services, a number of different approaches have been introduced, abandoned and changed since the early 1990s. For a number of years, fee-for-service payments, capitation and capitation with fund holding, diagnosis-related groups (DRG) and volume-based contracting systems all existed at the same time, depending on the area of health care, level of care and geographical location. More recently a unified payment system has been adopted for providers throughout the country.

Some health facilities have been privatized or partially privatized, leading to the establishment of a wide variety of property ownership in the system. Throughout the 1990s many innovations, such as the purchaser–provider split and family health care as the basis for PHC were introduced. Private supplementary insurance has also been introduced. Virtually every other aspect of the health care system has also been affected by the process of reforms, including the pharmaceutical sector, public health and dentistry, among others. One of the most important ongoing reforms is the Master Plan, or "Programme of Development of Primary and Hospital Care Services for 2005–2010", developed by the World Bank. The aim of this reform is to reduce administrative costs and improve the quality of health care services so as to improve patient access to health care."

3.2 Use of ICT in the Latvian healthcare sector

A recent (2007) status of the use of ICT by *general practitioners* in Latvia 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 Latvian country brief, we take over the following key findings:

"In terms of infrastructure, 88% of the Latvian GP practices use a computer. 85% of practices dispose of an Internet connection. In Latvia, broadband connections have not yet arrived in

force; they are however already used in 58% of GP practices. With respect to all three infrastructure indicators, Latvia holds a solid middle field position when compared to the other European Member States.

The relatively high availability of basic infrastructure as a prerequisite for eHealth solutions contrasts with very low actual use rates. Latvia scores well below the EU27 averages, when it comes to the use of ICT for eHealth purposes.

Of all applications under observation, storage of patient data either for administrative or for medical purposes is done most often. Around a quarter of Latvian GP practices store administrative patient information and roughly half of all practices store some type of medical patient data. Latvia scores slightly above average only when it comes to the storage of radiological data, which is used by 42% of Latvian GPs, in comparison to 34% on average in the EU27. All other usage rates with regard to local Electronic Health Records in Latvia are however still far below the EU average.

Computer use in consultation occurs only to a very limited extent. With only 3% of GPs actually using their PC for consulation purposes, Latvia comes in last in line with regard to this indicator. This percentage lags quite far behind the EU27 average of 66%.

Electronic patient data transfer is virtually non-existent among Latvian GPs. Up until now, only 1% of the GPs have used ePrescribing or received lab results from a laboratory via networked connections. Not one of the GPs included in the survey reported the transfer of medical or administrative patient data to other health professionals. While the results for the transfer of administrative and medical data are low even in comparison to the other EU member states, it should be noted that ePrescribing is still not a reality in most European Member States, with the exeption of Denmark.
1355 GPs have used their PC to transfer medical or administrative patient data to reimburser (HCISA) by Internet, using IPSEC protocol. Decision Support systems (DSS) have not yet been introduced in Latvia on a larger scale as only little more than 1% of the GPs covered in the survey reported using a DSS for either diagnosis or prescription.

The rather low usage rates of eHealth applications in Latvia are quite comprehensible when one takes into account the very recent history of eHealth policy measures in Latvia. A first eHealth strategy has only been decided on in 2005. At the same time an action plan aiming at the development of the information society was passed. This means that the IT infrastructure needed for a successful implementation of eHealth solutions will only be developed and enhanced during the years to come. In the domain of eHealth projects are in preparation that aim at the establishment of electronic health ~~insurance~~ cards, improved networking of health care institutions, the deployment of an electronic signature system and the improvement of digital literacy amoung health professionals."

3.3 National eHealth strategy

An overview of the Latvian eHealth policy can be found in the April 2007 ERA Report "eHealth strategy and implementation activities in Latvia" (Authors: Mariusz Duplaga, Mikołaj Leszczuk, Alicja Wirska, Sylwia Bukowczan and Anna Andrychiewicz): http://www.ehealth-era.org/database/database.html#latvia
For our Study, the following observations, adapted from this report, are important:

The Ministry of Health and the Secretariat of Electronic Government Affairs are involved in the process of definition of national eHealth policy. Latvian eHealth roadmap, the concept document titled "eHealth in Latvia" was approved by the Order No.560 of the Cabinet of Ministers of the Republic of Latvia on August 17, 2005. The concept document is available on the web page of the Ministry of Health:http://phoebe.vm.gov.lv/misc_db/web.nsf/bf25ab0f47ba5dd785256499006b15a4/17cb8c1218bf81cdc2257313001f391a/$FILE/e_vesel.pdf.The Ministry of Health was working on the implementation plan for the concept "eHealth in Latvia". It was planned that the implementation plan would be ready in 2007. The project of the implementation plan for year 2008-2010 is available at: http://www.mk.gov.lv/lv/mk/tap/?pid=30282955&mode=mk&date=2007-10-23.
Other documents relevant in this context:

- e-Latvia 2005-2008:

The Information Society programme "e-Latvia 2005-2008" aims to ensure the dynamic development and competitiveness of the country in the knowledge-based economy. Priority areas include e-Government, e-Learning, e-Business and welfare, eHealth, Broadband and access to services, and Security.

- National Development Plan of Latvia 2007-2013:

The document available at http://www.nap.lv/eng/ and contains also the sections on health information and eHealth.
The roadmap "implementation chain" (the main "players" expected to participate) is: Ministry of Health, Health Compulsory Insurance State Agency, Health Statistics and Medical Technologies State Agency, Public Health Agency, regional and state hospitals, GPs. The eHealth roadmap was made public in 2005, after approval by the Cabinet of Ministers of the Republic of Latvia. It has been further disseminated since August 2006.

According to the authors of the ERA Report the following priorities for actions are defined in the Concept "eHealth in Latvia":

- Establishment and implementation of electronic health card and electronic European health insurance card

Electronic European Health Insurance Card (eEHIC) should be adopted in 2008, replacing the paper-plastic based forms, ~~to ensure the EU citizens need for health treatment being in other Member States.~~ The e-Europe 2005 target is to build upon this, using Commission proposals for a common approach to patient identifiers, emergency data sets and electronic health record architecture, and create unified electronic European health insurance card. From August 1, 2005 only plastic European health insurance cards are available in Latvia that replaced previous paper E-forms.

- Implementation of health care institutions Electronic Health Record

At first the guidelines and standards for Electronic Health Record should be developed and approved by the statutory acts in Latvia. The establishment of separate information systems for big hospitals is foreseen to ensure the preparation and collection of the individual patients' electronic health records as there can be difficulties to start with centralized electronic health records storage system in Latvia. But in future it is expected to build such system that the electronic health records (clinical diagnostic results, provided treatment etc.) are prepared decentralized in each hospital but storage and accessibility to information are provided through centralized system.

Some progress is already achieved in respect to implementation of the Electronic Health Record. A presentation on the guidelines and the current status of the project was made on 27 May 2008. The presentation materials as well as other documents relevant to this project can be found on the web site of the Ministry of Health: http://www.vm.gov.lv/index.php?id=562&top=117. Also the project of the implementation plan for the concept "eHealth in Latvia" for the year 2008-2010 envisages the implementation of the Electronic Health Record.

- Improvement of linkage and connection between health care institutions' internal information systems, as well as the improvement of electronic data exchange with state health care registries, health authorities and managers

Firstly, the standard of data exchange is developed between the internal information system and health care registers as well as statistical IS of the health care institutions. Digital data transfer enables more effective networking among health care institutions in Latvia, ensure the fast information flow between the health care providers in case of emergency or disasters, and provide the health authorities and managers with high-quality administrative and clinical data for policy making and state actions. There are many new and good IS developed and established in Latvia (for example, communicable disease monitoring and control IS, medical devices market surveillance IS, unitary state's financial resources Management Information System (MIS), many statistical data registries and data bases etc.). Most of them are related to state function realization and are requested by European regulations.

The unitary state's financial resources MIS has been established in Latvia. MIS is the one of the biggest IS in Latvia. This system was created to ensure the proper state financial resources allocated for health care management and provide the Health Compulsory Insurance State Agency with data for organization of finance flow and for valuation of throughput. All major hospitals, many out-patient service providers, general practitioners and pharmacies are connected through Internet to MIS. This system is ensuring settlement for health care services and reimbursed medicines with hospitals, out- patient institutions, GPs, pharmacies, is providing support for financial managers and government, related to financial control and also statistics of patient flow (patient amount, diagnosis etc.) and provided health care services (treatment methods, reimbursement of medicine etc.). So, the managers and policy makers can receive important data about health system in Latvia. Moreover, the amount of paper documents, which need to be fill in, is reduced.

- Standardization of health related services and provision of health care services electronically and online – the definition of the chain of health care services and the implementation of IT technologies within the definite health care services with the aim to decrease paper work.

It includes such services as the appointments' (to general practitioner, health specialists, dentists and analyses) sign up or refusal, references, sign out, conclusion circulation, e-prescribing etc. The activities within this priority area save the time of patients and decrease the paper work for health professionals, provide the significant support for administration of health care institutions and management of financial resource as well as ensure the state control over medical prescriptions and drugs circulation.

As regards e-prescribing, at this stage the concept of e-prescribing, as well as procurement documentation is already prepared. Until now the state financing was the main source for this project. However, it is planned to use EU funds in this respect in the future. A presentation on the guidelines and the current status of the project was made on 27 May 2008. The presentation materials as well as other documents relevant to this project can be found on the web site of the Ministry of Health: http://www.vm.gov.lv/index.php?id=561&top=117.

Moreover, the project of the implementation plan for the concept "eHealth in Latvia" for the year 2008-2010 envisages the implementation of services standardization and electronization.

- Improvement of access of health related information for society and health care professionals

The main objective is to provide patients, health professionals, policy makers and other interested stakeholders with reliable and qualitative health information. One of the main activities is the establishment and maintenance of centralized health care website that should be created on quality criteria for health related websites established by the European Commission, based on consensus among specialists in this field, health authorities and

prospective users. The information should be separated between patients on the one side and health care specialists on the other side.

The home page for the medical professionals in Latvia has been developed. It contains information about the registered health care institutions, pharmacies, doctors' practices, and medical professional organizations etc. which are available in Latvia. It also provides access to many other registries like medicinal products register, links to other home pages related to health issue – the information that is necessary for practical work of medical specialists and managers. The maintenance of this home page is partly financed by the state agency – Health Statistics and Medical Technologies Agency. There is also possibility for every interested person or patient to ask questions to medical professionals. The doctor who is answering is responsible for the information provided for society.

Each governmental institution, which is working in the health field, has created their own home page where every person can find the information concerning particular institution, its functions and activities at national and international level. Many of health care service institutions and providers established their own home pages to inform the society about services and specialists available as well as its tariffs. There are home pages related to general public which has not been created by the government institutions and have the information in "simple language". The sanctions are also indicated in case of the information published in the internet is delusive or dangerous for health.

One may find useful links to some of the above mentioned home pages on the web site of the Ministry of Health http://www.vm.gov.lv/?id=161&top=161.

- Telemedicine development

It includes the establishment of centralized visual diagnostic IS, that foresees the visual diagnostic result of decentralized electronic preparing and provision of centralized storage and function circulation.

The application architecture for future health care results from the present architecture that will be supplemented with changes related to the implementation of new priorities and actions that are mentioned above. Currently, it is vital to develop common standards and integration platform in Latvia, so that the separate IS would be possible to integrate into one joint system in future, if necessary, and establish unified information exchange mechanism.

Presently it is essential to implement such preconditions to launch the eHealth implementation in Latvia as the implementation of citizens' electronic identity cards and the implementation of electronic signature, as well as the improvement of knowledge and skills of health care specialists concerning the information technologies` application in health sector. The electronic signature was introduced at the end of year 2006 and since then the Secretariat of

Electronic Government Affairs works on its dissemination. In 2006, document "Health Care Sector IS architecture" was prepared and is available on the web site of the Ministry of Health

http://phoebe.vm.gov.lv/misc_db/web.nsf/bf25ab0f47ba5dd785256499006b15a4/195448bbbf7b0975c2257313001f19e0/$FILE/VM-IS_arhit.pdf.

There are also some plans within the activities of HCISA in extending eHealth implementation to the field of social care.

Also the project of the implementation plan for the concept "eHealth in Latvia" for the year 2008-2010 envisages the development of the telemedicine.

Activities introduced in IT council of Ministry of Health that have been launched for making the national/regional eHealth roadmap more widely known are presentations in conferences and public information campaign. Funding scheme encompasses development and upgrade of information system as well as support of professional training. Ministry of Health acts as a responsible organisation for these dissemination activities. Some activities of this type were assigned to HCISA

Internet is used for the purpose of dissemination activities concerning the eHealth roadmap. An education programme will be prepared to introduce eHealth development. Means that are made available to the general public for expressing their opinions on eHealth policies and plans is eHealth section in home page of Ministry of Health (policy documents are made available for discussion and commenting).

3.4 Regulatory framework for patients' summaries

Latvia doesn't have specific legal provisions in the area of patients' summaries. It is planned to introduce the Electronic Health Record.

3.5 Regulatory framework for telemedicine

There are no specific legal provisions in Latvia with regard to telemedicine. However, in line with the implementation plan for the concept "eHealth in Latvia" for the year 2008-2010, the establishment of a telemedicine consulting center is planned.

3.6 Regulatory framework for electronic prescriptions

There is a special section for electronic prescriptions on the web site of the Ministry of Health. Among other documents, the document "Electronic prescription IS development concept" is available under this section. According to the concept currently the circulation of prescriptions is determined by the Cabinet Regulations No.175 as of 8 March 2005 on

Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions.
On 26 June 2007 the amendments to these Regulations were adopted, allowing the use of electronic prescriptions along with the paper prescriptions. According to point 55.1 of these Regulations, the content of electronic prescription complies with the requirements of the Regulations and it is made in accordance with laws governing electronic documents. However, the more detailed provisions on the procedure of use are not provided.
For more details refer to Chapter 8 of this report.

3.7 Overview of relevant legislation

The basic source in this domain is the concept document titled "eHealth in Latvia", which was approved by the Order No.560 of the Cabinet of Ministers of the Republic of Latvia on August 17, 2005. This is the main document determining the strategic directions as to the development of information technologies and telecommunications in the health care sector within 10 years time.
There are numerous legislative acts governing the health care system in the country. However, only some of them have direct references to eHealth activities. As mentioned above, one of the legislative acts incorporating provisions regarding electronic prescriptions is Cabinet Regulations No.175 as of 8 March 2005 on Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions.
Further relevant legislative texts relate to the practice of health care, such as Medical Treatment Act as of 12 June 1997 and Medical Practitioner Act as of 24 April 1997.

Of particular interest to eHealth are the laws on the protection of privacy in the context of personal data protection. In this regard, Personal Data Protection Law as of 23 March 2000 is relevant. Moreover, according to the information from the document "Electronic prescription IS development concept" the Ministry of Health has prepared the draft of the law on the protection of the rights of patients (see chapter 5.4. of this report).

Furthermore, indirectly relevant is also the law On State Social Insurance in force since 1 January 1998.

Also relevant is the Population Register Act (on the use of national personal identity number) in force as of 24 September 1998, as well as Electronic Documents Act (with regard to electronic documents and electronic signatures) in force as of 1 January 2003.

4 Regulatory framework for the healthcare profession

An overview of the regulatory framework for the medical profession in Latvia is presented on the basis of the HiT country profile (2008) for Latvia available at http://www.euro.who.int/Document/E91375.pdf, as well as the Medical Treatment Act, the Act on Regulated Professions and Recognition of Professional Qualifications and the Medical Practitioner Act.

4.1 Legal conditions for the practice of healthcare

The Medical Treatment Act, the Act on Regulated Professions and Recognition of Professional Qualifications and the Medical Practitioner Act set the legal conditions for the practice of healthcare in general and for the practice of medicine in particular. According to Article 10 of the Act on Regulated Professions and Recognition of Professional Qualifications, the diploma at the highest level of education, which is received within an accredited full-time program of studies of medicine, as well as the certificate of professional qualification, which could be obtained according to the provisions of the Medical Treatment Act, and inclusion in the Register of Medical Persons, is a basic requirement for proof of one's medical qualifications, for the right to work within the doctor's profession and for the right to practise within a particular specialty.

The minimum duration of studies to receive the diploma at the highest level of medical education is six years for medical doctors. After receiving the diploma, the doctor must continue studies within one of the doctor specialties in residency. The duration differs according to specialty, but on average it is three years.

If a doctor wants to gain the right to practice medicine, s/he must obtain the certificate of professional qualification. Certification of medical practitioners is delegated to respective practitioners' professional organizations. According to Article 29 Medical Treatment Act the certification of doctors (physicians) is done by the Latvian Physicians Association, whose web page is as follows: http://www.arstubiedriba.lv. Currently, the Cabinet Regulations No.431 as of 23 December 1997 on the Procedures for Certification of Medical Practitioners determine the respective certification and re-certification order. The associations determine the schedules for certification examinations, inform health care personnel about certification requirements, establish commissions for certification examinations, organize the examinations, and carry out the certification and re-certification. The associations are also responsible for publishing the list of certificated individuals in a separate publication or in the press. Re-certification takes place every five years.

According to Article 37 Medical Treatment Act a doctor is a medical practitioner who has acquired higher medical education of doctor according to the requirements of the Act on Regulated Professions and Recognition of Professional Qualifications and who with

scientifically grounded medical activities, directly or indirectly impacts on humans. The following acts are within the competence of doctors (physicians):

1) performing illness prevention, diagnostics, treatment and medical rehabilitation of patients;

2) evaluating illnesses and functionality restrictions caused by them on the body, activity and participation level;

3) studying origins of the illness and prevention options.

According to Article 39 Medical Treatment Act a doctor engages in a speciality (there may be several specialities) specified in his or her doctor's certificate. A doctor may engage in a sub-speciality, additional specialty or use a particular examination or treatment method only if he or she has a doctor's certificate in the primary specialty.

The Medical Practitioner Act determines that practising doctor is a certified doctor, who has registered doctor's practice according to the Act and performs medical treatment. The activities of practising doctor are the foundation of medical assistance. Furthermore, also foreigners may become a practising doctor in Latvia after receipt of permanent residence permit, doctor's certificate issued by Latvian Physicians Association and registration of doctor's practice according to this Act.

4.2 Control over the practice of medicine

The medical treatment in Latvia is supervised by the Ministry of Health and other institutions as specified by the law. In medical treatment institutions, the quality of professional health care and work disability expert examination is controlled by the Health Inspection. Moreover, the Medical Treatment Act provides for the operation of medical ethics committees. According to Article 14 of the Act, medical ethics committees are established by medical treatment institutions and professional organizations of medical practitioners. Such committees examine ethical matters related to the activities of medical practitioners and new medical technologies. As regards practising doctors, they are supervised by Latvian Physicians Association (according to the Articles of Association -Latvian Medical Association), which maintains respective doctors' practice register and is also entitled to terminate doctor's practice in cases foreseen in the Medical Practitioner Act.
According to the Articles of Latvian Physicians Association, the Association supervises the practice of doctor, to the extent such supervision is out of the scope of his direct supervisor. Moreover, the Association promotes medical ethics and controls its observance, as well as determines quality criteria for doctors' specialization and professional activities.
Latvian Physicians Association has its code of professional ethics. Latvian Doctors' Code of Ethics is made on the basis of International Code of Medical Ethics, which in 1993 was elaborated and approved by the World Medical Association. Among other statements, it is

noted that doctors should comply with the Declaration of Helsinki adopted in 1964 with addendums regarding the use of new therapeutic or diagnostic methods.

4.3 Professional liability

The Medical Treatment Act provides for liability provisions regarding improper use of medical technology. Among them, Article 36 of the Act states that medical practitioners are liable for the use of selected medical technology and consequences caused by it.
As regards practising doctors specifically, Article 17 of Medical Practitioner Act requires that practising doctors have compulsory civil liability insurance according to Cabinet Regulations No.177 as of 12 May 1998.
However, both the civil liability and the criminal liability of the doctor (physician) for damage or injury caused by improper performance of the duties entailed in the discharge of his professional functions, are governed by the general rules of civil and criminal law.

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. Article 45.3 of the Administrative Offences Code provides for administrative liability (a fine) for illegal disclosure of confidential information, which is acquired in the course of medical treatment.

According to Article 50 Medical Care Act, information regarding the medical treatment of a patient, the diagnosis and prognosis of a disease, as well as information obtained by medical practitioners during the medical treatment process regarding the private life of a patient and his or her closest relatives, is confidential.

At the moment the 1997 Medical Care Act is the main legislative act in Latvia with provisions relating to the rights of patients. According to these provisions, patients have the right to qualitative, considerate and respectful medical treatment and care; the right to information; and the right to confidentiality and privacy. According to the WHO Regional Office for Europe, this Act offers unsatisfactory protection of the rights of patients in a number of areas, particularly in the areas of confidentiality and privacy (WHO Regional Office for Europe 2002). In particular, there is no regulation of confidentiality in the case of minors; confidentiality applies only in the case of physicians (not nurses and other medical practitioners); and the right granted to medical practitioners to provide confidential information to colleagues for the purpose of achieving medical treatment is too broad and is subject to numerous questionable interpretations.

However, as mentioned above, a draft of the law on protection of the rights of patients, which could improve the situation and become the main legislative act safeguarding patients' rights,

has been prepared by the Ministry of Health and currently is being elaborated in the parliament.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Data protection in Latvia is governed by the Personal Data Protection Law (hereinafter referred to as **"the Law"**). The Law has been enacted in accordance with the Directive 95/46 of the European Parliament and of the Council of October 24, 1995 on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of Such Data (hereinafter referred to as **"the Directive**"). The Government Regulation on Mandatory Technical and Organizational Requirements with regard to the Protection of Personal Data Processing Systems (hereinafter referred to as **"the Regulation"**) is a supplementary piece of legislation that further elaborates the Law. The Regulation sets the standards of due care when dealing with personal data processing systems. Special regulation with regard to health related data is provided in the Medical Treatment Act.
Since the Law implements the Directive many definitions and concepts are identical or very similar to the Directive:

- the definitions of the essential concepts: personal data, processing, controller, processor, third party, recipient and consent (art. 2 of the Directive);
- the criteria for making personal data processing legitimate (art. 7 of the Directive);
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject's rights (art. 12, 14 and 15 of the Directive);
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive);
- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Latvian Data State Inspectorate can be read at http://www.dvi.gov.lv.

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

The Law differentiates between personal data and sensitive data. The term personal data is a general term used by the Law and it includes any information relating to an identified or identifiable natural person regardless of the type or format of such information. This definition includes personal data concerning health and thus all general rules and principles of the personal data processing according the Law are applicable to the processing of personal health data.

Personal data relating to criminal offences, convictions in criminal and administrative cases as well as relating to materials of court case files or court decisions can be processed only by specific persons defined in special laws and only in specific cases.

In addition, information related to health of the individual is defined as sensitive personal data. Although, as a general rule, it is prohibited to process sensitive personal data, nevertheless processing of the data relating to health of data subject, as a an exception, is permitted if it is necessary for health purposes, provision of health care services or administration of such services as well as distribution of medication (see details below).

According to the Law sensitive personal data is:

- data revealing person's race, ethnical origin;
- data revealing person's political, religious or philosophical beliefs;
- data revealing person's participation in trade union;
- data revealing information about persons health or sexual life.

Processing of sensitive data is forbidden by Article 11 of the Law. However, exceptions are applicable in the following situations:

- the data subject has given his or her written consent;
- it is so provided in the labour laws of Latvia and these laws guarantee the protection of personal data;
- it is necessary for the achievement of lawful and non-commercial goals of public associations but only if the personal data are related to the members of associations and they are not transmitted to third persons;
- it is necessary in order to protect the vital interests of the data subject or somebody's else interests, including life and health, and the data subject legally or physically is not able to give his or her consent;
- it is necessary for health purposes, provision of health care services or administration of such services as well as distribution of medication;
- it is necessary for the protection of interests and rights of individuals or legal persons in court proceedings;
- it is necessary for rendering of social assistance services and the service provider performs the processing of the data;
- it is necessary for the National archive and is performed by state archives or institutions that have been afforded the rights of a state storage institution by the director general of the state archives;
- it is necessary for statistical research carried out by the Central Statistical Board;
- the processing refers to such data which have been made public by the data subject itself;

- the processing is necessary in order to perform state governance functions or forming state information systems determined by law;
- processing is necessary for the protection of interests and rights of individuals or legal persons in the course of requesting payment under insurance contract.

The Law provides specific requirements for the processing of personal identification codes. Article 13 provides that personal identification codes can be processed if:

- the consent of the data subject has been obtained;

- the processing of the personal identification code arises from the purpose of the processing of personal data;

- the processing of personal identification codes is necessary for preservation of further anonymity of data subject; or

- the consent of the Data State Inspectorate has been obtained.

The Medical Treatment Act further stipulates that information about medical treatment of a patient, the diagnosis and prognosis of a disease (hereinafter – information regarding a patient), as well as information obtained by medical practitioners during the medical treatment process regarding the private life of a patient and his or her closest relatives, must be confidential (Article 50 (1) of the Medical Treatment Act).

Information by a medical practitioner regarding a patient may be provided upon written request within 15 days of such request to:

- other medical practitioners for the purpose of achieving the objectives of the medical treatment;
- the Medical Commission for Expert-Examination of Health and Working Ability; and
- the State Heath Inspection;
- the Health Compulsory Insurance State Agency for the purposes of administration of health care services;
- State Labour Inspection for accounting and investigation of accidents at work and professional diseases.

Furthermore, the information regarding a patient shall be provided to a court, the Office of the Prosecutor, the police, the responsible state institution for the child and family affairs (state inspectors for protection of the rights of the children), an Orphan's court (a parish court), as

well as to investigative institutions only at the written request of such institutions if there is a permission signed by the head of the medical treatment institution.

Article 50 (4) of the Medical Treatment Act stipulates that the information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his or her consent has been received.

State military service administrations of the Ministry of Defence are entitled to request from medical treatment institutions information regarding the state of health of the conscripts, reserve soldiers and reservists in accordance with the procedures prescribed by the Cabinet of Ministers (Article 50 (5) of the Medical Treatment Act).

State Fire and Rescue Service is entitled to request from the treatment institutions statistical information. Treatment institutions are prohibited to disclose personal data to State Fire and Rescue Service (Article 50 (6) of the Medical Treatment Act).

A medical practitioner may refuse to provide the above information over the telephone or other means of electronic communication. As indicated above, while processing personal health data, medical practitioners must observe general rules on processing of personal data.

Personal data concerning health as defined by the Law or information regarding patient as defined by the Medical Treatment Act is not further elaborated in Latvian law or practice. This concept has not been also discussed or described by the doctrine. In practice it would be possible to refer to the definition of the Council of Europe recommendations regarding the processing of health data: “The meaning of the term "personal data concerning health" (…) includes information concerning the past, present and future, physical or mental health of an individual. The information may refer to a person who is sick, healthy or deceased. This category of data also covers those relating to abuse of alcohol or the taking of drugs.”

5.3 Information and access rights of data subjects

Specific regulation pertaining to the information and access rights of data subject to the personal data concerning health is provided by the Medical Treatment Act and Medical Practitioner Act (see chapter 6 of this report). The Law provides general rules, which apply to personal data concerning health as well.
As a general rule according to the Law, data subject has the right to obtain all information that has been collected concerning himself or herself in any system for personal data processing, unless the disclosure of such information is prohibited by law in the field of national security, defense and criminal law. Furthermore, a data subject has the right to obtain information concerning those natural or legal persons who within a prescribed time period have received information from a system administrator concerning this data subject. In the information to be provided to the data subject, it is prohibited to include State institutions, which administer

criminal procedures, investigatory operations authorities or other institutions concerning which the disclosure of such information is prohibited by law.
A data subject also has the right to request the following information:

- the designation, or name and surname, and address of the system administrator;
- the purpose, amount and method of the personal data processing;
- the date when the personal data concerning the data subject were last rectified, data deleted or blocked;
- the source from which the personal data were obtained unless the disclosure of such information is prohibited by law; and
- the processing methods utilised for the automated processing systems, concerning the application of which individual automated decisions are taken.

A data subject has the right, within a period of one month from the date of submission of the relevant request (not more frequently than two times a year), to receive the above-described information in writing free of charge.
According to Article 16 of the Law a data subject has the right to request that his or her personal data be supplemented or rectified, as well as that their processing be suspended or that the data be destroyed if the personal data are incomplete, outdated, false, unlawfully obtained or are no longer necessary for the purposes for which they were collected. If the data subject is able to substantiate that the personal data included in the personal data processing system are incomplete, outdated, false, unlawfully obtained or no longer necessary for the purposes for which they were collected, the system administrator has an obligation to rectify this inaccuracy or violation without delay and notify third parties who have previously received the processed data of such.
Individual does not have above-described rights if the processed data are used only for the needs of scientific and statistical research or the establishment of Latvian national archive holdings in accordance with regulatory enactments and, on the basis of such, no activities are carried out and no decisions are taken regarding the data subject (Article 17 of the Law).
The refusal of the system administrator to provide information to a data subject or to make requested amendments, rectifications or deletions may be appealed by the data subject to the Data State Inspectorate.

5.4 Other relevant rules regarding personal data protection

More elaborated rights of persons with regard to their personal data concerning health are envisaged in the draft Patients Rights Act, which has been accepted by the government and submitted to the parliament in 22 February 2005. The draft has not been adopted by the parliament yet. At this point in time the draft has been accepted in the second reading. Most likely the law will be adopted by the parliament during the second half of 2008. The draft will supplement the current regulation on patients' rights with regard to access to information and processing of patients' personal heath data. In many instance it reiterates or provides more detailed regulation on patients' rights. It foresees that the patient will have rights to receive

information from the doctor about his health conditions, diagnosis and prognosis of the disease, method of treatment and its results, information about possible risks and side effects in the course of the treatment, possibilities of analogous medication choices, health check and treatment plan. This information should be provided in understandable format, explaining medical terms, and considering patients age, maturity and experience. The draft law also foresees that a patent will have certain rights in receiving his medical documentation and requesting to make some amendments, provided the original information is preserved. Specific rules regarding disclosing of patient's information are envisaged as well.
Human Genome Research Law stipulates specific rights of a gene donor with regard to the processing of personal data. According to Article 11 or the Human Genome Research Law a gene donor has right:

- to become acquainted or refuse to become acquainted with the data stored in the genome database regarding the gene donor;
- to prohibit the supplementation, renewal or verification of the description of his or her state of health in the genome database;
- to revoke his or her consent to being a gene donor at any time. In such a case the tissue samples, the description of the state of health of the gene donor and any information related to the identification of a person shall be destroyed.
- to limit the scope of the research of his/her genome.

Furthermore, the Human Genome Research Law addresses taking of tissue samples and preparation of descriptions of the state of health of donor, use of genealogies, storage and taking out of Latvia the tissue samples, descriptions of DNA and descriptions of the state of health of donor, issuance of descriptions of DNA, as well as destruction of personal data, tissue samples, descriptions of DNA and descriptions of the state of health of the gene donor.

6 Rights and duties of healthcare providers and patients

Currently, the rights and duties of healthcare providers and patients are regulated in the Medical Treatment Act and the Medical Practitioner Act as of year 1997. However, for the future, as indicated in the previous chapter, a draft law on protection of the rights of patients, which will become the main legislative act safeguarding patients' rights, is in the process of adoption by the Latvian parliament.

6.1 Scope of the law

According to the Medical Treatment Act patient means "a person who is being treated or who is registered with a medical practitioner and, if necessary, is being treated". Healthcare means "the complex of measures for ensuring and maintaining health." The healthcare of pregnant woman and child is priority. Medical treatment means "professional and individual prophylaxis, diagnosis and medical treatment of diseases, and rehabilitation and care of patients". Medical practitioners are "persons who have a medical education and who are engaged in medical treatment", thus including doctors (physicians), dentists, midwives, functional specialists, nurses and their assistants. The Act covers also medical treatment support persons, who are not entitled to do medical treatment, but who are directly involved in the healthcare.

6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is specified in Article 25 Medical Treatment Act. Namely, it is stated that in the medical treatment process, a patient is obliged to comply with the instructions of medical practitioners and with the internal procedure regulations of the medical treatment institution. During the period of medical treatment, a patient may not perform activities that may harm his or her health.

6.3 Right to quality care

According to Article 6 Medical Treatment Act a patient has the right to receive qualitative medical treatment and care. Moreover, on the basis of Article 22 of the Act, patients have the right to receive an evaluation of the quality of the healthcare received in accordance with the procedures set out in regulatory enactments.

6.4 Right to free choice

According to Article 6 Medical Treatment Act a patient, his or her closest relatives or lawful representatives (trustees, guardians) have the right to choose a medical treatment institution located in Latvia and a medical practitioner for the diagnosis and medical treatment of illnesses and injuries, and rehabilitation of the patient.

6.5 Rights related to information about the state of health

According to Articles 20 and 21 Medical Treatment Act patients have the right to receive information from a doctor in a way that they can comprehend regarding the diagnosis of his or her illness, examination and medical treatment plans, as well as regarding other medical treatment methods and prognosis. Moreover, a patient has the right to receive information regarding the medical treatment process from other medical practitioners at the level of their competence.

Furthermore, Article 41 of the Act states that a doctor must obtain the consent of a patient for medical treatment. Therefore the doctor has a duty to provide information to the patient in a comprehensible way regarding the diagnosis of the illness, the planned examination and medical treatment, as well as regarding other medical treatment methods and prognosis. The doctor has a duty to explain and inform the patient of the possible effects and complications of the disease. The doctor must inform the patient of possible side effects of the prescribed medical substances or medical treatment methods. However, the doctor may provide incomplete information to the patient regarding the diagnosis and prognosis of the disease if he or she considers that such information may cause deterioration of the state of health of the patient. Article 24 Medical Practitioner Act has the same provisions.

6.6 Right to give consent

As mentioned above, a doctor must obtain the consent of a patient for medical treatment. Moreover, according to Article 23 of the Act a patient has the right to refuse, in full or in part, examination or medical treatment offered by certifying such refusal with his or her signature. If a patient is a minor or a person who due to his or her state of health is unable to understand the consequences of his or her actions, family members, but if such do not exist, the closest relatives or lawful representatives of the patient (trustees, guardians) have such rights and liability for the decisions taken. The doctor has a duty to explain to the patient, his or her family members, closest relatives or lawful representatives (trustees, guardians) the consequences of such refusal. If a patient has accepted a treatment plan, he or she is responsible for observing all instructions of the medical practitioner related to the medical treatment and care.

However, Article 49 of the Act provides that in cases where delay may endanger the life of a patient and where it is impossible to receive the permission of the patient, his or her family members, or if such do not exist, closest relatives or lawful representatives (trustees, guardians), the medical practitioner has a duty to take emergency measures – examination, medical treatment and surgical intervention--within the scope of his or her competence. In such cases the examination and medical treatment plan must be approved and a decision taken by a doctors' council (except in cases where first aid or emergency medical care has to be provided). The doctor has a duty to notify the Orphan's court or parish court for the purpose of protecting the interests of a minor regarding the decision taken by the council with respect to further examination and medical treatment of the minor patient.

Article 25 Medical Practitioner Act, in its turn, determines that in case a patient, his or her family members, but if such do not exist, the closest relatives, trustees or guardians refuse in full or in part consultation, examination or medical treatment, and if as a result of such refusal deterioration of the state of health of the patient or death is possible, the practising doctor is obliged to explain it to the patient or other persons concerned and to record the possible consequences of such refusal. If the patient or the persons concerned do not change their decision, the practising doctor is obliged to encourage the patient to attend other doctor.

6.7 Rights related to the patient's medical record

According to Article 59 Medical Treatment Act the procedures for keeping medical records in medical treatment institutions are specified by the Cabinet Regulations No.265 of 4 April 2006.

According to the Regulations medical and bookkeeping documentation as regards receipt of primary and secondary health care and emergency medical care (hereinafter – medical records) constitutes a single information unit. The medical records are batched and kept by a family doctor (primary health care internist, pediatrist).

If a patient changes a family doctor, the family doctor hands over to the family doctor chosen by the patient full medical records about the patient.

Medical records done in an out-patient medical treatment institution constitute an out-patient's card. One part of medical records of the out-patient medical treatment institution is a summary, which contains the following information: final diagnosis, information about previous illnesses (also infectious diseases) and injuries, main surgical and invasive procedures, inimical and allergic reactions and regularly used medicine. The summary is located in one place in the out-patient's card. If important information about the patient is located also in another medical record, the summary contains a written notice about the place where such information can be found.

Medical records done in an in-patient medical treatment institution constitute a patient's illness history.

Information about the health care service provided to a patient by other medical treatment institution or medical practitioners, is added to the patient's medical records by the treating doctor.

Medical records of a patient signed out of the in-patient medical treatment institution are finalized and handed over for storage at a filing cabinet of the in-patient medical treatment institution not later than 14 days after the signing out.
The Regulations set the requirements in respect to the content of medical records. Namely, medical records include information which ensures the identification of a patient, confirms the diagnosis, substantiates examinations and medical treatment methods, as well as precisely shows the treatment results.

Patient is entitled to acquaint himself or herself with information about him or her included in medical records and stored at a medical treatment institution by attending a treating doctor at the medical treatment institution. The treating doctor is obliged to provide in a comprehensible way to the patient information included in the medical records about the patient's diagnosis, examination and medical treatment plan, the other medical treatment methods and illness prognosis, as well as to explain the meaning of the records in the medical documents.
Moreover, a patient is entitled at the presence of a medical practitioner or an employee of a medical treatment institution to write a note at a designated place in the medical records, if he or she considers that the records contain erroneous or imprecise information.
If a treating doctor or a head of a medical treatment institution has determined that a part of medical records contains information, which has to be particularly protected, such information is kept separately on technical information carriers. In this case there is a notice in the medical records indicating the place, where such information can be found.
Head of a medical treatment institution ensures the protection of medical records and information included therein against erasure, change of facts and unauthorised use and appoints a medical practitioner responsible for the protection of the said medical records and information.
Medical practitioners involved in the medical treatment process of a patient during the business hours of the medical treatment institution ensure that persons not involved in the medical treatment process do not have access to the patient's medical records and information included therein. During the non business hours medical records and information included therein are kept in special safe places.
In respect to the quality of medical records the Regulations state that medical records have to be true, full, legible and without corrections. However, if due to well grounded reasons any corrections are needed, the initial information must be saved and attached to the corrections.
Only medical practitioners are eligible to make records in the medical documents.
Furthermore, electronically prepared reports about examinations of a patient are signed by the treating doctor and attached to medical records. Medical documents may be prepared electronically in accordance with the laws on preparation of electronic documents.
Storage term of medical records varies from 1 to 75 years as of the last record made depending on type of the record.
The Regulations apply to all medical treatment institutions in Latvia, including doctor's practices.

6.8 Right to protection of privacy and intimacy

According to Article 50 Medical Treatment Act information regarding the medical treatment of a patient, the diagnosis and prognosis of a disease (information regarding a patient), as well as information obtained by medical practitioners during the medical treatment process regarding the private life of a patient and his or her closest relatives, is confidential.

6.9 Right to representation in case of incompetence

Article 23 Medical Treatment Act provides that a patient has the right to refuse, in full or in part, examination or medical treatment offered by certifying such refusal with his or her signature. If a patient is a minor or a person who due to his or her state of health is unable to understand the consequences of his or her actions, family members, but if such do not exist, the closest relatives or lawful representatives of the patient (trustees, guardians) have such rights and liability for the decisions taken. The doctor has a duty to explain to the patient, his or her family members, closest relatives or lawful representatives (trustees, guardians) the consequences of such refusal.

7 Identity management in the health sector

A coordinated identity management system for the Latvian healthcare sector including the identities of patients, healthcare professionals and other stakeholders is not yet available.
Official registers of local healthcare professionals and institutions with online electronic search service are available in Latvia.
Healthcare professionals are registered in the official register of healthcare professionals, established by the Ministry of Health. This register contains identification dataset, consisting of persons information (first and last name(s), personal code, number of register, specialization), contact information, education, information about certificate of healthcare professional, speaking languages.
Healthcare institutions are registered in the official register of healthcare institutions and its certification. Register is established by the Ministry of Health and contains name of institution, number of registration, information about certificate, structure and branches, addresses.
Electronic databases of healthcare institutions and healthcare professionals' registers are available at the Health Statistics and Medical Technologies State Agency website (http://www.vsmtva.gov.lv/web/lv/datubazes/index.aspx).
As regards any schemes using identifiers for healthcare providers, the identifiers are used only at the local information systems of healthcare institutions.
Identity system for the Latvian healthcare sector including the identities of patients is not available. Today person's only official identifier is person attestant document - passport, but in fact also driving license is used.
In respect to government involvement, the Cabinet of Ministers approved E-health strategy and action plan, which provides several actions referring to patient and doctor identification. Secretariat of Special Assignments Minister for Electronic Government Affairs in 2008 established national electronic ID card development work group.
As regards the role of patient cards or other tokens in the health sector, persons ID documents are used when healthcare professionals (specialists) are visited.
There are two basic legal acts setting security requirements with regard to authentication in the health sector. Namely, the Medical Treatment Act sets the requirements for healthcare institutions, medical data processing. The Personal Data Protection Act, in its turn, sets the requirements for personal data processing.
As to the role of electronic signatures, since October 4, 2006 E-ME http://www.e-me.lv offers electronic signature certificates. Since January 1, 2004 state and municipal authorities should accept electronically signed documents.
Electronic signature is not popular because for usual people costs are too high (34 EUR+additional price for signature with time stamp and 150 EUR with unlimited time stamps usage for 2 years period), so in general e-signature is used only in government sector.
In future e-signatures will be used as identifier for national level e-health information systems.

8 Electronic prescription

As mentioned above, the Cabinet Regulations No.175 as of 8 March 2005 on Manufacture and Storage of Prescription Forms, as well as Writing out and Storage of Prescriptions set the legal framework on prescriptions by healthcare providers.
Moreover, there are legal provisions that explicitly refer to electronic prescriptions. Namely, on 26 June 2007 the amendments to these Regulations were adopted, allowing the use of electronic prescriptions along with the paper prescriptions. According to point 55.1 of these Regulations, the content of electronic prescription complies with the requirements of the Regulations and it is made in accordance with laws governing electronic documents. However, the more detailed provisions on the procedure of use are not provided.
As regards the possibilities for prescribers to guide patients to a particular provider, point 3 of the Regulations determines that advertising is prohibited on a prescription (also on the reverse side of a prescription). Moreover, according to point 29 of the Regulations a medical treatment practitioner is prohibited to receive and store prescription forms on which the name of medicinal products is indicated.
In respect to procedures for writing out prescriptions it is stated that a prescription must be written out on the official forms (Annexes 1 and 2 to the Regulations), taking into account the requirements referred to in Annex 3 of these Regulations for completing the prescription forms. A prescription must be written out in a clearly legible handwriting or by using a computer, or other technical means which ensure clear and unmistakable data perception.
According to the Regulations the State Agency of Medicines (http://www.vza.gov.lv) is the institution implementing the electronic prescriptions project. In line with the Agency's report on 27 May 2008 the project is implemented in 3 stages: the pilot stage, the first and the second stage.
The pilot stage foresees the implementation of the project at some doctor's practices and pharmacies. Later on, at the first stage the circulation of paper prescriptions with barcode and signed by a doctor is envisaged. Afterwards, the transition to fully electronic prescriptions and cooperation with Electronic Health Record will take place.
As a result of implementation of the project, doctors will be able to make electronic prescriptions in the portal or in their own system of doctor's practices, to use already entered information about patient, to select medicines from different lists and patient's history, to see instructions of use and descriptions of medicines, to see information about the fact of handing out the prescribed medicine to the patient and warnings about interaction of medicines.
For pharmacists, in its turn, the project will allow not to enter information about compensated medicines. Moreover, prescriptions in the form of ID barcode will give a chance to quickly enter information in the pharmacy's system, and also information about medicines handed out in the pharmacy's system will be entered by using barcode scanner. Thus, the work will be done in the pharmacy's system or in the portal of electronic prescriptions.
Finally, for patients, the electronic prescriptions will allow in a case of loss of prescriptions not to visit a doctor again and in special cases it will be possible to make prescriptions via

telephone. The history will be available in the portal of electronic prescriptions and there will be a chance to receive warnings on the possible interaction of medicines as well.

9 General assessment

There are many good foreruns as regards the development of interoperable eHealth in Latvia, both from the regulatory and implementation aspects. Two of such examples are the development of electronic prescriptions system and Electronic Health Record. However, work still has to be done, and support at the EU level would be important factor.

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27 June 2008

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