SMART 2007/0059

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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE - THE CZECH REPUBLIC

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European Commission
Directorate General Information Society

Brussels

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1 Documents

1. Applicable Documents

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

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

3. 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 infections, 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.

2.1 Acronyms

EHR	Electronic Health Record
eID	Electronic Identity
eIDM	Electronic Identity Management
GP.....	General Practitioner
HiT	Health in Transition
OCSP	Online Certificate Status Protocol
PKI	Public Key Infrastructure

NRN	National Register Number
SIS	Social (security) Information System
SSCD	Secure Signature Creation Device
SSIN	Social Security Identification Number
TTP	Trusted Third Party

3 Introduction

3.1 General overview of the Czech healthcare system

A comprehensive overview of the Czech healthcare system can be found in the Czech Republic HiT country report published by the European Observatory on Health Systems and Policies (written by Martina Rokosová and Petr Háva) - http://www.euro.who.int/Document/E86823.pdf (109 p.). This report was published in 2005 and healthcare system in the Czech Republic is now in a transformation process. We will try to inform on the main things that has already changed – the Ministry of Health is planning to adopt other changes but it is not sure that these changes will really be accepted by Parliament and in which form.

From the executive summary of the report mentioned above, we extract the following information (updated according to the initiatives of our government which have already been confirmed by valid legal acts):

"The three main features of the health care system in the Czech Republic are as follows: social health insurance with universal membership, funded through contributions by individuals, employers and the State; diversity of provision, with mainly private ambulatory care providers and public hospitals which have contractual arrangements with the insurance fund; and joint negotiations by key players on coverage and reimbursement issues. The Government supervises the negotiations and ultimately has to approve the result; it may act on its own if the parties fail to agree."

"The Ministry of Health directly manages and controls certain healthcare establishments and bodies engaged in the protection of public health, but also large hospitals with regional or supra-regional spheres of influence."

"State administration at district level was abolished at the end of 2002. In certain cases, communities are the owners and operators of small hospitals. Several dozen small hospitals have been privatized in the form of commercial companies, but continue to be financed from statutory health insurance. The network of outpatient services and pharmacy services has been nearly entirely privatized. The owners of those facilities are doctors, pharmacists, and other operators." Privatization of small hospitals is continuing and 2/3 of all hospitals were privatized in 2007. Our government plans to privatize also big hospitals, including teaching hospitals and specialised hospitals, but there is aversion against this step.

"Health care in the Czech Republic is provided primarily on the basis of statutory health insurance, which is currently provided by nine health insurance funds. The largest health insurance fund, the GHIF (General Health Insurance Fund, Všeobecná zdravotní pojišťovna), has 77 district branches – one in each former district of the Czech Republic."

"Any person with a permanent residence in the Czech Republic is entitled to health insurance, as are people who do not have their permanent residence there but are employed by an employer whose registered base is in the country. Every health insurance fund has the

obligation to accept any client who meets the conditions for participating in statutory health insurance. Anyone who does not meet the conditions for participation in statutory health insurance may take out contractual health insurance. An entitled person has the right to choose any health insurance fund once every 12 months."
"The system of financing is based on solidarity and equity. It is financed by contributions from individuals, employers and the State (on behalf of the unemployed, pensioners, children and dependants up to 26 years of age, students, women on maternity leave, men serving in the military, prisoners, and people receiving social welfare). Approximately 56% of the population is insured by the State. The State also acts as guarantor of the system."
"Contributions are defined by law as a percentage of wages (before tax): employees pay 4.5% and employers 9% (13.5% altogether). There is a ceiling on contributions, which is set at about six times the average salary in the Czech Republic. This makes the funding system mildly regressive. The self-employed pay the same total percentage (i.e. 13.5%) but only on 35% of their profits."
In the beginning of 2008 the Ministry of Health established a new regulatory fee – circa 1,2 EUR for every visit of a physician, 1,2 EUR for 1 item on a prescription, 2,4 EUR for 1 day in hospital and 3,6 EUR for visit of an emergency ambulance. There is a limit of 200 EUR for 1 person – if it is reached, insurance fund refunds everything over the limit to the person. Instead of this fee patient doesn't pay anything more to the physician (the patient pays only additional payment for medicine that is more expensive than medicine stated by Ministry of Health decree on medicine reimbursement No. 63/2007 Coll.). Health care professionals are paid from health insurance funds.
"Health insurance funds are not permitted to make a profit. Any surplus goes to a special account called the Reserve Fund. The health insurance funds are no longer allowed to offer additional services to their clients, as this had contributed to the bankruptcies. In cases of financial difficulty, only limited assistance is available from the State, but the insured are protected from loss of coverage by the existence of the GHIF safety net. The Ministry of Labour and Social Affairs, the Ministry of Finance and the Ministry of Health all participate in the boards of the funds, while the Ministry of Health is responsible for supervision, which, in practice, at least initially, has been fairly weak."
"Health care services are covered by the health insurance funds, while sickness benefits (i.e. sick pay) are paid from the state-run social security fund, which is not part of the national budget."
"In every case, the cheapest available treatment is fully covered. The respective health insurance fund, represented by a review doctor, can examine the circumstances and agree to the full reimbursement of a more expensive treatment." Our government plans to let patients to decide if they want more expensive treatment, but patient will pay expenses which are over the cheapest treatment – this is not established standardised process for this option today.
"There is a clear division in earnings between physicians in private practice and those employed by the State. The latter, mostly working in state-owned hospitals, are salaried and earn a wage that is above the Czech average. Physicians in private practice are paid according

to the services they deliver. There are now, however, limits on the volume of services (enforced in 2001) so that specialists are not reimbursed without limits."

3.2 Use of ICT in the Czech healthcare sector

There are no recent and reliable data on the use of ICT by specialists, hospitals or pharmacies in the Czech Republic – this kind of data is not collected and monitored. A recent (2007) status of the use of ICT by *general practitioners* in the Czech Republic 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 Czech country brief, we take over the following key findings:
"In terms of infrastructure, 82% of the Czech GP practices use a computer. 63% of the practices are connected to the Internet. Around 40% of the Czech GP practices use a broadband connection. These figures, that are only slightly below the EU27 averages, place the Czech Republic at the tail end of a cluster of average performers.
The Czech Republic displays its best eHealth performance in the area of patient data storage, the use of a computer for consultation purposes and the use of a Decision Support System (DSS). DSS are particularly well established in the Czech Republic. They are used for diagnosis or prescribing purposes in 72% of the Czech GP practices, a share that clearly exceeds the EU27 average of 62%."
"Both administrative and medical data are stored in around 70% of Czech GP practices. The share of Czech practitioners storing the different types of individual medical patient data correspond more or less to the averages to be found in the EU27. This indicates that in the Czech Republic the electronic storage of patient data is only moderately common. Two thirds of the Czech GP practices use a computer in consultation with their patients. This figure comes very close to the EU27 average of 66%.
The transfer of electronic individual patient data via the Internet or dedicated networks is not yet well established in the Czech Republic. Electronic administrative patient data is routinely transferred to other carers by merely 6% of Czech GP practices, to reimbursers only by 13%. However while only 6% exchange medical data with other carers via networked connections, already one out of four practices receives laboratory results this way.
ePrescribing is still not a reality in most European Member States. This holds true for the Czech Republic as well. None of the GPs in the survey reported using ePrescribing. The low level of electronic data transfer between Czech GPs and reimbursers or other care professionals can be attributed to the lack of an adequate network infrastructure up to now. The government plans to developed and establish such an eHealth network in the near future."

3.3 National eHealth strategy

An overview of the Czech Republic eHealth policy can be found in the June 2007 ERA Report "eHealth strategy and implementation activities in the Czech Republic":
http://www.ehealth-era.org/database/database.html#czech, but this document wasn't updated

after new government introduced new strategy for eHealth (project establishing eHealth platform) in the Czech Republic.
For the Study, the following information is important:
There was not a real eHealth strategy of the Czech Republic until now. All successful projects that exist and are being used are based on activities of private companies or were realised as isolated projects of public administration bodies. In October 2007 the Ministry of Health established a "Interdepartmental coordinating committee for eHealth implementation in the Czech Republic" that has to coordinate eHealth projects. This committee published its objectives (available only in Czech language - http://www.mzcr.cz/Pages/426-cile-projektu-ehealth-v-ceske-republice.html) and detailed plan (available only in Czech language - http://www.mzcr.cz/Pages/350-vecne-zamery-projektu-ehealth.html) how to reach it. Because this project is very new, there was almost nothing implemented of planned projects until now, but there exist functional systems or projects that will be used as a basis for implementation of these projects.

Projects of our government in the field of eHealth are (with short description what is planned and information on what already exists):

1. Electronic form of health documentation
Unified platform for electronic health records sharing and exchanging between health services providers has to be implemented. There will be defined data structure of electronic health records that has to be exchanged. Electronic form of health documentation with paper form must be equal; this measure must be implemented by legislative change.
Nowadays it is possible to keep health documentation in electronic form; it must be electronically signed with advanced electronic signatures, every day a security copy" of the records must be created "and after 1 year must be created an "archival copy". These requirements are not easy to implement, so it is expected that this will be changed (currently a draft amendment of the act on archiving is prepared where will be defined the process of archiving of electronically signed data – there must be kept record on result of verification of electronic signature with the signed data in a trustworthy form and only under this condition it will be possible to keep the document in electronic form for a long term. Maybe these requirements will be used also for health documentation.). There exist systems in which is kept health documentation in electronic form but the most common practice is to have documentation saved in information system and print it and keep it in paper form.
"The nationwide system of the patient medical record in electronic form accessible through Internet and provided by company IZIP Inc. is one of the most successful initiatives in the area of eHealth in the Czech Republic. The main objective of the service was to develop a medical database of insured patients who consent to include their data to the public information network through Internet. The database structure includes medical documentation entered to the IZIP system by the physicians taking care of the patient in various care facilities. The main assumption is that only the patient has access to data for reading it in the database and he or she may authorise other person to browse his or her medical data. In this

way, upon the content of the patient, every health care institution or professional taking care of the patient may share information on provided services. The IZIP service is operational from several years now (http://www.izip.cz/index.php?lang=eng)."
It is planned that all existing systems will be updated to be able to share health records according to the definitions of a new platform for health documentation. New data standards have to be based on international standard (now it is only local data standard) used in EU.

2. ePrescribing
This project has to permit the exchange data on prescription between prescribing physician, pharmacy, health insurance funds and finally also patients. It has to decrease the costs caused by prescription of the same medicine by more than one physician (if the patient agrees on sharing of his data) and to eliminate the risk of issuance of a different medicine than the one required (caused by unreadable prescription). There will be better overview for planning of medicine policies.
ePrescribing is not used in the Czech Republic, as it is written above. Usually prescription is handwritten or printed from computer in paper form. Pharmacist re-writes data about the medicine and data about the patient to the information system to get reimbursement from health insurance fund. It causes mistakes.

3. Electronic ID cards of insurers (patients) and health services provider (health professionals)
Design and implementation of electronic ID of insurer and health service provider, together with implementation of electronic system of payment will ensure monitoring of data flows in health sector, better address payments in health sector and lower administrative costs.
In the Czech Republic people use plastic EHIC card with data required by EU represented only in visual form, without chip. There were a few pilot projects on electronic ID cards in the health sector, of which the most important are:
"The cluster of projects conducted within PHARE programme focused on the utilization of smart cards for the electronic identification of persons by the Ministry of Health and the General Health Insurance Fund. The project was than increased by Ministry of Labour and Social Affairs to get information they use for welfare services.
The activities conducted within the projects included:
· Design of the smart card (with contact chip) and determination of its contents
· Provision of the card readers to ambulances, hospitals and part of physicians as well as pharmacies
Czech Republic participates also in the NETC@RD project. Pilot implementation sites were selected in Prague and Moravia for this project."
There is plan to use other data carriers than standard smart card, e.g. cell phone SIM card, to lower costs and to make it more comfortable for patients to use it.
Health services providers are not uniquely identified because registers of health professionals are not prepared for this service.

4. Health registers and resort data consolidation

Health registers

This project has to change the way of creation, development, operation and usage of all types of health registers. There has to be an established technological basis for secure and effective communication between subjects that provide data to registers and the register itself. Data has to be automatically validated before it is saved to a register.

Nowadays there exists a lot of registers in the health sector. Basically these registers can be classified as:

- Hygienic registers, used for supervision and epidemiology
- Health registers, concentrating information on diseases and medical performances (e.g. medical examination, operation)
- Organisational and informational registers, used for administration and integration of data of other registers, for assessment of efficiency of healthcare or assessment of information resources

Registers can be also classified as national (it is mandatory to administer them according to legal act) and specialised (created after experts communities initiatives).

Some of registers have different administrators, are operated on different places, technological platforms and their development is not coordinated enough as needed.

Resort data consolidation – data interface standardisation

Data exchange and sharing will be easier because unified communication interface for all health sector networks via definition of data standard that will be compatible with international (and mainly EU) standards will be created. This data exchange is needed to be integrated to European structures of healthcare and to share health data. This project is closely connected with almost all other projects of eHealth in the Czech Republic mentioned in this overview.

Today, for health data exchange and sharing the "Ministry of Health data standard" (Datový standard MZ ČR is used. More information is available only in Czech language at http://ciselniky.dasta.mzcr.cz/). This standard (data structure) is created for exchange of data about patients between information systems of health establishments. The standard is designed for creation of communication interfaces in hospital information systems, laboratory information systems, general practitioner information systems and other health information systems. This data structure is defined in XML language.

The Ministry of Health data standard is accepted by all key market players on local market, but it is not internationally accepted – it is used only in Slovakia.

This standard is used for exchange of patient medical records, to transfer data about citizens health state and about activities of heath establishments to so called "National health information system" (Národní zdravotnický informační systém, NZIS, this system is concentrating data from many health information systems, health registers etc., more information can be found at http://www.uzis.cz/info.php?article=1&mnu_id=2000) and also to transfer data on drinking and supply water inspection etc.

The Ministry of Health data standard has to be modified to be compatible with standards used in EU. This will be helpful to share health information across EU and this would lead to be easily integrated into EU healthcare system. This measure will also help to provide better

information systems in the Czech Republic, because it will be easily possible to use information systems created in other EU countries and our IT developers will be able to sell their products in other countries without data structure modifications.

5. Classification schemes, clinical decision and Health Technology Assessment
This project has to define general scheme of structure, content and algorithms for standards, recommended process, clinical protocols etc. This project will serve the optimisation of usage of current clinical information from applied medical research. The goal of this project is also to optimize the quality of healthcare. This project has to change the approach to the usage of standards, guidelines, clinical protocols and decision support systems for healthcare. The project in the field of Health Technology Assessment (HTA) is concentrated on secure and effective usage of defined and auditable medical technologies – this is important for the next development of health information systems.
Today classification systems are used (mainly DRG – diagnosis related groups) but often not in defined structure used universal and standardised way. There is an absence of classification systems for attendance diagnosis, rehabilitation, one-day surgery etc. Decision support systems are also used, but usually only on local basis and it is impossible to compare these systems. HTA is not used in general practice, only in local projects.

6. Health portal, education and telemedicine
An health portal has to increase the awareness of citizens about the healthcare system, quality of provided services, healthcare providers, patient rights, healthcare financing, qualified information about diseases, health, pharmaceuticals etc. This portal will also have a secured part with authorised access to patient medical records for citizens. Information on this portal will be gained from registers, the system of health records and the ePrescription system.
The health portal will serve also health professionals, because there will be available documents for them. There will further be a prepared e-learning system for pre/post-gradual education. The health portal will support the development of telemedicine in the field of distant assessment of results, consultation with other experts or decision support system, interconnection of patients, physicians, attendants, other healthcare providers and patients' family members.
"Now there are many health-related portals available targeting various groups of users in the Czech Republic. Most of them provide general health information, disease-specific information and information on services. The „Virtual health-portal" Ordinance (http://www.ordinace.cz/) is a comprehensive service addressing following areas and functionalities:
· A selected extract of most common diseases
· Self-treatment of less serious complaints
· Health-related issues: medical terms, surgery, etc.
· Answer to specific questions, answered by specialized staff
· Online pharmacy
· Discussion forum

· Up-to-date reports
Medvik (http://www.medvik.cz) is a virtual library of medical and health-related documents developed from 2004. It is funded and managed by several medical establishments: the National Medical Library, the Institute of Clinical and Experimental Medicine, the Institute for Postgraduate Medical Education and the Institute of Hematology and Blood Transfusion."
The MedGate is the name of a global health-related Internet portal funded by the Ministry of Education, Youth and Sports. It is expected that this portal will become access point to numerous databases and digitized collections, this time it has only database of Medvik. Furthermore, it should also play the role of medium connecting many medical establishments. None of existing portals has complex information that is generally reliable – quality of published information is not verified. Existing portals with information about health will have the possibility to get certification from Ministry of Health. All existing on-line resources of health information will be published in the overview on the health portal.

3.4 Regulatory framework for patients' summaries

The Czech Republic doesn't have legal provisions in the area of patients' summaries and it is not planned to have it. It is planned to have all patient health records available on the health portal (and this will require legislative changes to state obligations and requirements on system administration, user identification, etc.) for authorised persons (if the patient agrees) and maybe after this is available it will be useful to define structure of patients' summaries with the most important data. After legislation in the Czech Republic will make it possible to have all patient health records available through one access it will also be legislatively possible also to have accessible patient summaries.

3.5 Regulatory framework for telemedicine

There are no specific provisions in the Czech Republic with regard to telemedicine – there are only requirements on health documentation storage, medical secret and on personal data protection (and of course there are requirements on healthcare provider, but it is not in contradiction to telemedicine).
There exists many applications of telemedicine in the Czech Republic and there haven't been practical problems with the regulatory framework in case of telemedicine applications until now.

3.6 Regulatory framework for electronic prescriptions

There exists legislation for electronic prescriptions in the Czech Republic. The Act on Pharmaceuticals no. 378/2008 Coll. (zákon o léčivech) in Section 81 establishes an "Electronic Prescription Central Repository". Section 82 of this act makes it legally possible

to use electronic prescription. This act is new (issued 6 December 2007) and the central repository has to be in operation on 6 December 2008. There is also decree No. 54/2008 Coll. on the Pharmaceuticals Prescribing Procedure, Data Indicated on Prescription and on Rules for Prescription Usage (vyhláška o způsobu předepisování léčivých přípravků, údajích uváděných na lékařském předpisu a o pravidlech používání lékařských předpisů) where is also stated procedure for electronic prescription.
While this system will be prepared, it is not possible to prescribe in electronic form – there must be at least a paper form together with electronic form of the prescription. Usually electronic prescription is not used. But there are few local systems (usually hospitals with pharmacies in the same locality) where it is practically used – but the patient must be informed that he can use only enumerated pharmacies (or he has to get original receipt) and the prescription is stored by the physician and after few days he gives pack of prescriptions to the pharmacy. Or there are used other solutions to get the same result – parallel existence of receipt in electronic and paper form.

3.7 Overview of relevant legislation

As it is clear from the text above, legislation in the Czech Republic doesn't have any legislative act specialized on eHealth – almost all projects that are planned and need legislative change to be applied will require to amend the existing acts (or new acts or decrees will be created but not only for eHealth, also for "non-e-health"). Patient's personal data are generally protected according to the Data Protection Act No. 101/2000 Coll. (zákon o ochraně osobních údajů).
The main act for thehealth sector, that defines and states (within other provisions that are not relevant for eHealth) requirements for electronic health documentation and establishes the National Health Register and other registers used in the health sector, is Act No. 20/1966 Coll. on People's Healthcare (zákon o péči o zdraví lidu). It is planned to replace this act by a new act on Health Services and Conditions for Health Services Provision – there currently exists a draft of this act. This new act will be in case of electronic health documentation and National Health Register very similar to existing legislation; there will be established new health registers and the way of electronic health documentation maintenance has to be more precisely specified.
There exists also a decree on Data Exchange with the National Health Information System No. 552/2004 Coll. (vyhláška o předávání osobních a dalších údajů do Národního zdravotnického informačního systému pro potřeby vedení národních zdravotních registrů), where it is stated who is obliged to send data into which health register. Another decree concretizing requirements given by Act on People's Healthcare is decree No. 385/2006 Coll. on Health Documentation (vyhláška o zdravotnické dokumentaci). In this decree are given requirements on maintenance and content of health documentation. This decree doesn't say anything about health documentation in electronic form and it seems that projects of eHealth in the eHealth strategy will have change of this situation as one of the outputs.

Another important act is the above mentioned Act on Pharmaceuticals no. 378/2008 Coll., with requirements for electronic prescription and Electronic Prescription Central Repository. To this act belongs decree No. 54/2008 Coll. on Pharmaceuticals Prescribing Procedure, Data Indicated on Prescription and on Rules for Prescription Usage, which defines requirements on electronic prescription more detailed.
Act No. 48/1997 Coll. on Public Health Insurance (zákon o veřejném zdravotním pojištění), where is stated what information must be on health card, insurer ID number, requirements on exchange of information needed for supervision of healthcare in the Czech Republic – information about provided healthcare. For collecting of these data there is established Information Center for Health Insurance – health insurance funds and healthcare providers send data to this information center.
With the issue of eHealth is connected also the legislation on personal identification – it is given by Act on Citizen's Evidence and Birth Numbers (zákon o evidenci obyvatel a rodných číslech) No. 133/2000 Coll. (amendment of this act and issuance of new act on Citizen's Register is planned by Ministry of Interior – there is planned change of form of personal identification). Also legislation on electronic signature (Act No. 227/2000 Coll., on Electronic Signature, zákon o elektronickém podpisu) and act on archiving (Act No. 499/2004 Coll., on Archiving and Document Management Systems, zákon o archivnictví a spisové službě) is relevant for eHealth.

4 Regulatory framework for the healthcare profession

The regulatory framework for the healthcare profession contains more legal acts, as described below.

4.1 Legal conditions for the practice of healthcare

The regulation of education of healthcare professionals is stated by Act No. 95/2004 Coll., on conditions of acquirement and adoption of expert qualification and specialized qualification for practicing of health profession of physician, dentist and pharmacist (zákon o podmínkách získávání a uznávání odborné způsobilosti a specializované způsobilosti k výkonu zdravotnického povolání lékaře, zubního lékaře a farmaceuta). This act is in compliance with all European directives in this field. There are decrees with specific requirements on education of healthcare professionals – decree No. 392/2004 Coll., on minimum requirements for accredited health magisterial study programs general medicine, dental medicine and pharmaceutics (vyhláška, kterou se stanoví minimální požadavky na akreditované zdravotnické magisterské studijní programy všeobecné lékařství, zubní lékařství a farmacie); decree No. 394/2004 Coll., on details on practice of attestation examination and other examinations for medical qualifications verification (vyhláška, kterou se upravují podrobnosti o konání atestační zkoušky, zkoušky k vydání osvědčení k výkonu zdravotnického povolání bez odborného dohledu, závěrečné zkoušky akreditovaných kvalifikačních kurzů, aprobační zkoušky a zkušební řád pro tyto zkoušky); decree No. 395/2004 Coll., examination rules for attestation examination for physician, dentist and pharmacist (vyhláška, kterou se stanoví zkušební řád pro atestační zkoušky a pro aprobační zkoušky lékaře, zubního lékaře a farmaceuta).

The practice of medicine is regulated by Act No. 20/1966 Coll., on People's Healthcare. This act regulates healthcare provision, including medicine (including dentistry), nursing and rehabilitations of human patients and pharmacy both their curative and preventive aspects. No person may practice medicine unless he holds a legal diploma of physician. This monopoly is exclusive, which means that with the exclusion of all others, physicians are competent to practice medicine. Physician can practice only activities for which he/she has attestation for specialization.

To practice medicine in the Czech Republic, the following requirements have to be fulfilled:

- Possession of the legally required diploma (general medicine): diplomas awarded in other EU Member States are assimilated in accordance with the provisions of Council Directive 93/16, Council Directive 78/686, Council Directive 85/433, Council Directive 78/687 and Council Directive 85/432.
- Attestation diploma for specialization in subject field in which the physician wants practice.
- Every practicing physician must be member of the Czech Medical Chamber or The Czech Dentist Chamber.

- The person who wants to practice medicine must speak Czech language enough to practice his profession.

Preventive medicine belongs to the legal monopoly of physicians. Self-help or self-care is not considered as illegal practice of medicine (it is not an act *vis-à-vis* another human being). On the other hand the taking of blood samples is an act of medicine that may only be performed by physicians or nurses at the request of a physician. Using appliances, for instance to measure blood pressure, heartbeat, pulsation, etc. is not considered as (illegal) practice of medicine in the context of self-examination or self-care. Whenever the appliance is used to examine the state of health of another human being, it can be considered as an act of medicine reserved to physicians.

4.2 Control over the practice of medicine

The practice of medicine in the Czech Republic is supervised by the Czech Medical Chamber. The Chamber includes all physicians who are permanently residing in the Czech Republic and who are inscribed on the list of the provincial chamber where they have their permanent residence. Nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in the Czech Republic only if they are registered on the list of the Czech Medical Chamber. Every physician is subjected to the jurisdiction of the Chamber for his activities on the Czech territory.
The most important function of the provincial councils of the Order of Physicians is to ensure observance of the rules of professional conduct for medical practitioners and the upholding of the reputation, standards of discretion, probity and dignity of the members of the Order.
The Czech Medical Chamber is an independent, non-political autonomous professional organisation responsible for the interests, the professionalism, the ethics and the honour of the medical profession.
The Czech Medical Chamber
· Controls its members if they practice their profession in conformity with the highest professional standards, as well as with the principles of medical ethics and with the law;
· Serves as the guarantor of professionalism an the part of its members and certifies satisfaction of the requirements for the practice of medicine;
· Reviews and defends the rights and the professional, social and economic interests of its members;
· Defends the professional honor of its members;
· Maintains the register of its members.
Members of the Chamber have their rules they have to respect. It includes ethics code, where rules for practising of medicine are, for the individual relations between a physician and his patients, colleagues, dentists, pharmacists and allied health professionals.
More information about the Czech Medical Chamber can be found at http://www.lkcr.cz/langwebview.php?item.id=66386&do[load]=1&hmp=1&l=en.

4.3 Professional liability

The act No. 20/1966 Coll. on People's Healthcare states that healthcare institution is liable of damage caused by fault of their employees. The liability of damage is regulated by Civil Code (No. 40/1964 Coll., Section 420) in a way that the subject who is liable has to prove that he did not caused the damage. Healthcare institution has to prove that their health professionals did not committed the fault.

Professional liability of a physician is currently not governed by special laws, with the exception of disciplinary liability, in the Czech Republic. This means that both the civil liability and the criminal liability of the 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. Disciplinary liability of the physician is not governed by law; it is governed by the Czech Medical Chamber disciplinary regulations.

Civil liability of a physician arises when an obligation is not fulfilled. Physician is responsible only to the healthcare institution for which he/she works according to labour law provisions. Probably if the physician causes big damage he/she will be suspended from the Czech Medical Chamber and this practically means that he/she cannot practice medicine. The Czech Medical Chamber can also penalize the physician. Physician is personally liable also for bodily harm and non supplying help according to criminal law.

Usually there are causes when the physician did not provided care according to "lege artis". Other causes that are common – when the physician did not provided care according to "well-informed approval" of the patient. Common causes in the health sector are also connected with damages caused by equipment, preparation or substance used during provision of healthcare. There are also causes because of break of obligation of secrecy or because of break of obligation of first-aid provision.

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. Section 55 of the act No. 20/1966 Coll. on People's Healthcare lays upon a physician and other healthcare workers (also including nursing and paramedical personnel) obligation "to keep discretion on matters that he gets knowledge during practicing his profession, with the exception of cases when he tells the matter with approval of the treated person".

The physician is obliged to notify matters connected with clinical assessments or tests of healthcare means according to Act on healthcare means, No. 123/2000 Coll. (vyhláška o zdravotnických prostředcích). This obligation is not replaced by above mentioned obligation of People's Healthcare Act.

Obligation to keep discretion according to People's Healthcare Act is not applied for the physician in criminal procedure in necessary scope for defense. This obligation is also not applied in court or other body procedure if the subject of the procedure is plea between him (or his employer) and patient or other person applying the right for compensation of a damage or personal protection in connection with healthcare provision.

Section 178 of the Criminal Code lays upon every person liability for disclosure of personal data that she got in connection with public administration provision. Liability for disclosure of personal data is laid also on every person who discloses personal data that she got in connection with provision of her profession, employment or function, if she has obligation to keep discretion according to legal act.
This statement of Criminal Code is applied in case of physician or any other person who works in healthcare sector discloses confidential information about the patient.
Lawyers have the opinion that this statement is "time-bomb" of medical legislation in our country because in the Czech Republic it is common during doctor's rounds that the physician is presenting sensitive data about the patient in public (other patients can hear it). But until now there wasn't such court proceeding.
There are no special requirements for so called "shared secret" but as it is written above, duty of secrecy is applied for every healthcare professional, incl. physicians, dentists, nurses and paramedical personnel.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 1992 the Czech Republic has general legislation protecting the individual with regard to automatic processing of personal data. The law of 29 April 1992 on Protection of the Personal Data in Information Systems has been repealed in 2000 and a new law of 4 April 2000, the Personal Data Protection Act, No. 101/2000 Coll., in order to transpose the provisions of the European Directive 95/46/EC was adopted. An English version of this act is available at http://www.uoou.cz/index.php?l=en&m=left&mid=01:01.

Generally speaking the data protection act in the Czech Republic is very similar to the European directive. In the Czech Republic the data protection act is in accordance with the directive and there are also parts specifying details of data protection.

The definitions from article 2 of the Directive are extended with definitions of e.g. sensitive data, anonymous data, personal data collection, personal data preserving, personal data blocking and personal data liquidation. The definitions of terms taken from the Directive are almost the same as in the Directive.

The rules regarding quality from article 6 of the Directive and criteria for making personal data processing legitimate from article 7 of the Directive are implemented as rights and obligations in processing of personal data. Also these statements are more concrete than these in the Directive. There is specifically stated what has the controller to do with data which are not accurate.

The information to be given to the data subject according to article 10-11 of the Directive, the data subject's rights according to article 12, 14 and 15 of the Directive, confidentiality and security of processing according to article 16-17 of the Directive and notifications to supervisory authority according to article 18-19 of the Directive are implemented in the Personal Data Protection Act almost the same.

Competencies and status of the supervisory authority (in the Czech Republic it is the Office for Personal Data Protection, http://www.uoou.cz/index.php?l=en&m=bottom&mid=01) according to article 20-21 and 28 of the Directive are also the same as it is required by the Directive. In the Personal Data Protection Act is defined also the organisational structure of the Office, with the president of the Office and inspectors of the Office and there are requirements on these positions. Activity of the Office is specified more detailed.

Liability for damages according to article 23 of the Directive and transfer of personal data to third countries according to article 25-26 of the Directive is implemented the same way as it is written in the Directive.

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

Legislation in the Czech Republic (Personal Data Protection Act, No. 101/2000 Coll.) transposes article 8 of the Directive – processing of special categories of data, as processing

of sensitive data. There are not separate provisions for any type of data; rules for processing of data concerning health are the same as rules for processing of other sensitive data.

Sensitive data are defined in Section 4, letter b) as:

“personal data revealing nationality, racial or ethnic origin, political attitudes, trade-union membership, religious and philosophical beliefs, conviction of a criminal act, health status and sexual life of the data subject and genetic data of the data subject; sensitive data shall also mean a biometric data permitting direct identification or authentication of the data subject;”.

Section 9 regulating processing of sensitive data is formulated as:

“Sensitive data may be processed only:

(a) if the data subject has given his express consent to the processing. When giving his consent, the data subject must be provided with the information about what purpose of processing, what personal data, which controller and what period of time the consent is being given for. The controller must be able to prove the existence of the consent of data subject to personal data processing during the whole period of processing. The controller is obliged to instruct in advance the data subject of his rights pursuant to Section 12 and 21,

(b) if it is necessary in order to preserve the life or health of the data subject or some other person or to eliminate imminent serious danger to their property, if his consent cannot be obtained, in particular, due to physical, mental or legal incapacity, or if the data subject is missing or for similar reasons. The controller shall be obliged to terminate data processing as soon as the above mentioned reasons cease to exist and must liquidate the data, unless the data subject gives his consent to further processing.

(c) if the processing in question is in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of health sector pursuant to a special Act, or it is related to assessment of health in other cases provided by a special Act,

(d) if the processing is necessary to keep the obligations and rights of the controller responsible for processing in the fields of labour law and employment provided by a special Act,

(e) if the processing pursue political, philosophical, religious or trade-union aims and is carried out within the scope of legitimate activity of a civil association, foundation or other legal person of non-profit nature (hereinafter referred to as the "association"), and which relates only to members of the association or persons with whom the association is in

recurrent contact related to legitimate activity of the association, and the personal data are not disclosed without the consent of data subject,

(f) if the data processed pursuant to a special Act are necessary to carry on sickness insurance, pension insurance (security), accident insurance, state social support and other state social security benefits, social services, social care, assistance in material need and social and legal protection of children, and if, at the same time, the protection of these data is ensured in accordance with the law,

(g) if the processing concerns personal data published by the data subject,

(h) if the processing is necessary to secure and exercise legal claims,

(i) if they are processed exclusively for archival purposes pursuant to a special Act, or

(j) if it is the processing under special acts regulating prevention, investigation, detection of criminal activities, prosecution of criminal offences and search for persons."

The following comments can be made to section 9 of Czech law:

- Processing personal data concerning health in defined situations (letter b, c and f) is possible without the consent of the data subject.
- It is possible to process sensitive data concerning health only if the person processing these data (including persons responsible e.g. for health insurance) needs it for his profession.
- Personal Data Protection Act is general and more requirements on healthcare data processing are stated by act on People's Healthcare.
- It is possible to let other person (family members or other persons) be informed about his state of health, but it must be based on patient consent (written or if the patient is unable to write, there must be witness confirming the consent of the patient). By default this information is provided to family members. It is also possible to forbid getting the information for any person.
- There were cases in the Czech Republic when healthcare service provider didn't want to give health documentation to family members after unclean death of the patient – and according to our legislation it was possible to refuse to give the health documentation to family members after death of the person. In 2007 the act on People's Healthcare was amended and it is obligatory to let "related person" (family members, partner) access to health documentation after death of the patient and to be informed about the reason of the death.

- It is possible to refuse to tell information about health of the patient (e.g. results of laboratory investigation) on the telephone if the healthcare professional is not sure about the caller.
- Access rights to health documentation have, according to act on People's Healthcare (in the scope needed to fulfill specific action):
    - healthcare professionals (incl. physicians, dentists, pharmacists) in connection with healthcare provision
    - members of the Czech Medical Chamber when investigating disciplinary cases
    - audit physicians of health funds in scope given by law
    - authorized expert in the field of health in scope needed to elaborate expertise specified by court or bodies acting in criminal procedure (police, public prosecutor)
    - physicians from administration bodies in the health sector delegated to solve concrete complaints, suggestions on review, and suggestions on administrative proceeding
    - physicians authorized to create expert statement to solve concrete complaints, suggestions on review, and suggestions on administrative proceeding by Ministry of Health or regional authority
    - physicians of State Office for Nuclear Safety
    - members of experts commission
    - authorized healthcare professionals of public health protection bodies
    - physicians of social security administration bodies when reviewing state of health and invalidity (for allowances and social security services, etc.)
    - state employees and employees of healthcare establishments ensuring for healthcare establishments personal data processing
    - employees ensuring activities of National Health Information System connected with personal data processing
    - Public Defender of Rights (Ombudsman) in connection with his investigation
    - inspectors of Air Accidents Investigation Institutes when investigating reason of air accident
    - employees of State Institute for Drug Control when performing supervision

5.3 Information and access rights of data subjects

General rights of data subject in Personal Data Protection Act are almost the same as it is written in the directive. Specific rights of the patient (as subject of data about his health) are stated in act on People's Healthcare.

A patient has a right to

a) get access to all information collected in health documentation of his person or in other records connected to his state of health; in case of authorized psychological methods and description of therapy with psychotherapeutic means he has the right to

access to information about description of symptoms, diagnosis, description of therapeutic policy and test results interpretation,
b) look in documents according to letter a) in presence of healthcare professional; in case of records of authorized psychological methods and description of therapy with psychotherapeutic means patient can view records with description of symptoms, diagnosis, description of therapeutic policy and test results interpretation,
c) get extract, transcript or copy of documents stated in letter a); in case of records of authorized psychological methods and description of therapy with psychotherapeutic means patient has right to get extract, transcript or copy of parts of documents regarding description of symptoms, diagnosis, description of therapeutic policy and test results interpretation,
d) designate person who could be informed about his/her state of health or express prohibition to inform any person about his/her state of health. Patient can use this right during the entrance to healthcare institution or anytime after it. Patient designates if the designating person (who can be informed about his/her state of health) can get access to his/her personal data according to letter b) and c). Patient can anytime withdraw designation and prohibition. Right to designate person and prohibition to inform cannot be applied to process according to clause 10 and 11 (cannot change access rights to documentation to subjects described in chapter 5.2) and it cannot be applied in cases stated by other laws. If the patient cannot designate persons who have to be informed about his/her state of health because of his/her state of health, the right to access to information have related persons.

Physicians must inform the patient or his/her legal representative about his/her rights.
In patient healthcare documentation must be written the designation of the person or prohibition to inform according to letter d), eventually about withdrawing of the designation of person or prohibition to inform. This record must be signed by the doctor and the patient. If the patient cannot sign the record because of state of health but is able to express his/her will, record can be sign by physician and one witness. In the record must be stated way how the patient expressed his/her will and medical reasons why patient couldn't sign the record.
Right to access to information about state of health of the patient who died, reasons of the death and results of medical section, if it was done, right to look in the documents in presence of health professional or to other medical records, right to get extract, transcript or copy of documents have related persons, eventually persons designated by the died patient.

5.4 Other relevant rules regarding personal data protection

There are also rules for other usage of personal data related to health. These data are used mainly for statistical purposes, but it must be anonymous before it is used in information systems other than national health registers. Everything important about personal data protection is written above.

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the law on act on People's Healthcare No. 20/1966 Coll. – this act deals with many aspects of health services and one of them are rights and duties of healthcare providers and patients.

6.1 Scope of the law – with accent on rights and duties

Healthcare in the Czech Republic according to act on People's Healthcare includes medical education of the people, sanitary activities and contagious diseases control, cure and prevention, company doctors preventive care, rescue service, care in spa, pharmaceutics, reviewing of ability to work of invalid persons.
Health professionals in the current state of the legislation are: physicians, dentists, pharmacists, nurses, midwifes, ergotherapists (curing by work), radiology assistants, medical laboratory technicians, medical-social workers, optometrists, orthoptists, public health protection assistants, orthotist-prosthetists, nutritional therapists, dental technicians, dental hygienists, health rescuers, pharmacy laboratory technicians, biomedical technicians, radiographers, psychologists in health and clinical psychologists, clinical speech therapists, physiotherapists, radiological physicists and other healthcare workers pursuing paramedical profession under professional supervision or direct guidance and other professional workers in health care and dentists without university level. Practitioners of non-conventional medicine are not considered as health professionals.

6.2 Duty of the patient to co-operate

There is proclamation in act on People's Healthcare that every citizen has to try to live in a way to be healthy.
In act on Public Health Insurance No. 48/1997 Coll. there is statement that insured person has to cooperate during medical performance and supervision of medical process and to comply with medical regime defined by the physician. In the same law is written that if the insured person is not cooperating during hospitalization, she/he can be released of the medical establishment.

6.3 Right to quality care

Quality healthcare is priority of our government. Ministry of Health created "portal of quality" where will be published information about quality of services of health establishments (available only in Czech language - http://portalkvality.mzcr.cz/). Quality of care means care in accordance with standards determined by the current state of science. In the Czech Republic there were no rules and criteria for measurement of quality (and existing methods were not used enough) and this has to be changed.

6.4 Right to free choice

According to section 9 of the act on People's Healthcare, the patient has the right to freely choose his health professional and health establishment and to change that choice; except for some restrictions in determined cases (e.g. persons in prison cannot choose). There is special law on choice of physician for soldiers.

6.5 Rights related to information about the state of health

A patient has the right to receive from the health professional all information collected in health documentation of his person or in other records connected to his state of health; in case of authorized psychological methods and description of therapy with psychotherapeutic means he has the right to access to information about description of symptoms, diagnosis, description of therapeutic policy and test results interpretation all relevant information necessary to assess his state of health and his prognosis.
Information is not provided to the patient if patient explicitly requests not to know. The form of explicit request not to know is not stated, but it is recommended to use written form.

6.6 Right to give consent

There is specified that medical examination and treatment is done with consent of the patient, or if it is possible to expect that consent. Patient must be informed about the disease and about results, alternatives and risks of treatment, to be able to decide to give consent. Consent must be given expressly, except when the health professional, after having adequately informed the patient, can reasonably infer consent from the patient's behavior. If the patient refuses needed care, physician asks him/her for written statement.
If medical examination and treatment is needed to save life or health of children whose parents refuse to agree, physician has right to decide on performance of the treatment.
It is possible to perform medical examination and treatment without consent of the patient and if it is according to type of disease needed also to hospitalize the patient

- if it is disease that can be according to special law obliged to cure
- if the patient has symptoms of mental disease or intoxication and is dangerous for him/herself and his/her neighborhoods
- if it is impossible to ask the patient for his agreement and treatment is urgent needed to save patients life or health
- if the patient is infection disease carrier.

6.7 Rights related to the patient's medical record

The patient has the right to a medical record, carefully updated and safely stored by the health professional. Every health professional should keep a medical documentation about every patient to whom he provides healthcare services. Medical establishment is obliged to keep medical documentation.
Act on People's Healthcare contains basic rules for processing of patient's medical record – it is possible to use paper or electronic form of medical documentation. There are defined

requirements on electronic form of medical documentation. There is requirement on physician to pass the documentation to another physician if the patient chose him.
Decree on Medical Documentation No. 385/2006 Coll. contains requirements on content of medical documentation (there are minimum requirements on content of medical documentation for different parts of medical documentation) and requirements on shredding of medical documentation. There are defined periods for archiving of parts of medical documentation – it must be archived during 5 years up to 150 years depending on type of record and if the patient is dead or alive.
Patients have the right to access their own medical records and to obtain a copy of their medical records as it is written in chapter 5.3 of this questionnaire, at cost price, as soon as possible and not later than 30 days following the request. Every access to medical documentation must be recorded in the medical documentation.

6.8 Right to protection of privacy and intimacy

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health given by law. The right to the protection of their intimacy is written only in ethical codex. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent.

6.9 Right to representation in case of incompetence

The law on People's Healthcare contains rules to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity. Minor patients who are deemed capable of reasonably grasping their situation may exercise their rights on their own behalf.

7 Identity management in the health sector

A co-ordinated identity management system for healthcare sector in the Czech Republic including the identities of patients, healthcare professionals and other stakeholders is not yet available. Because there don't exist eIDM general system in the Czech Republic, problem of eIDM in health sector has to be solved within the project of eHealth strategy. There was a discussion on theme if it will be possible to use general personal ID card as it is planned to be issued for citizens. It is mainly political problem and maybe these two projects will finally have consolidated result.

7.1 Overview

Identity management of patients in the Czech Republic healthcare system is based on birth numbers. Usage of birth numbers is explicitly restricted by law and it is possible to use it in health sector in defined cases. This number is included in medical documentation of the patient to identify him/her. This number is used when medical establishment sends data to National Health Information System. The National Health Information System maintains health registers (content of these registers is shortly described in chapter 3.3 point 4).
There exists register of physicians, dentists and pharmacists where are these healthcare professionals identified with their birth numbers.
Identification of legal persons (and all economic subjects) is based on their ID numbers issued by the Czech Statistical Office.

7.2 The EHIC Card

In the Czech Republic patient uses to identify himself his citizen card and European Health Insurance Card (EHIC) issued by health insurance fund where he is insured. This card is plastic card without any mean that could be used for electronic identification. On this card there is written birth number of the insured person for unique identification of this person.

7.3 Patient identifier

As noted above, identification of the citizen is primarily based on his birth number. Use of this number is strictly monitored, and subject to prior approval by inspectors of Office for Personal Data Protection. This number is used for personal identification almost in all information systems in the Czech Republic and usage of it in health sector is not seen as a good solution. This is planned to be changed according to eHealth strategy.
There has to be established register of health insurance insurers where will be administered electronic ID. Project of patients' electronic identification will be in accordance with European project eEHIC.
Just a remark for identification of patients in hospital – many hospitals started to use barcodes for identification of hospitalised patients. There were cases of substitution of patients (esp. in narcosis when it is impossible to communicate) that lead to damage for the patient and then

also to the hospital. But this type of identification is not used for exchange of patients' data in information systems, it is used only locally.

7.4 Authentication of healthcare professionals

Healthcare professionals (physicians, dentists and pharmacists) are registered in register of physicians, dentists and pharmacists, established by the Institute of Health Information and Statistics of the Czech Republic. This register contains information about the qualification and the specialization of a physicians, dentists and pharmacists identified through their birth number. There is also information on medical establishment for which the person works or if the person has private praxis.
Information about other healthcare professionals (paramedical workers with professional qualifications) is available through register of health establishments, which is managed also by the Institute of Health Information and Statistics of the Czech Republic (Ústav zdravotnických informací a statistiky ČR, http://www.uzis.cz/info.php?article=1&mnu_id=2000&lng=en). In this register there are not identified persons – medical establishments send only total numbers of all physicians and of all paramedical workers with professional qualifications to the register.
The register of physicians, dentists and pharmacists will be used as a base for system of identification of healthcare professionals in the Czech Republic. Now these registers serve mainly for statistic and assessment purpose.
In eHealth strategy it is planned to use eEHIC card to get access to eHealth portal, where will be accessible medical documentation – for health professionals and for patients. Details of identification and authentication with eEHIC card aren't specified yet, as well as other security requirements.

7.5 Exchange of health-related data

Nowadays there exists exchange of health-related data between medical establishments and National Health Information System (respectively registers) and more frequently exchange of data between Health Establishments (respectively physicians) and health insurance funds. It is also possible to communicate between information systems of different medical establishments or laboratories.
Communication between medical establishments and National Health Information System is usually done one time in a year. It is done by electronic means – there are two possibilities of delivery of data, first is to fill the form in XML602 Filler (it is possible to use data standard where is defined XML structure that has to be send to National Health Information System and use it for export of data from information system of physician or medical establishment) and than to send it via Central Repository of Reports to National Health Information System. Second possibility is to send data carrier (CD, DVD) with the filled form by post. In exceptional situations it is possible to send paper form.
Medical establishments (or physicians) usually communicate with health insurance funds to get reimbursed for performances they have done. Every health insurance fund has its portal

(smaller health insurance funds have together one portal). There is used advanced electronic signature based on qualified certificate to confirm that data sent to the health insurance fund are correct and to ensure integrity. Health insurance funds in cooperation with certification service provider organised action of getting qualified certificate for lower price – for circa 4 EUR. This usage of qualified certificates caused that there are many physicians in the Czech Republic who have qualified certificates.
Communication between information systems of two medical establishments is not so common. Usually there exists communication between hospital information system and laboratory information system of cooperating hospital and laboratory. For this type of communication there is used data standard published by Ministry of Health (available only in Czech language - http://ciselniky.dasta.mzcr.cz/). Identification of patients in data structures defined by this data standard is done with birth number. This standard is based on XML and it is planned to change it to be in compliance with standard HL7. Security level is based on creator of the application, they have to respect requirements stated by legislation – but there is no specific technical requirement, only general that can be applied by more methods.
As it was written above, it is planned to create health portal where will patients and physicians have access to all needed information, where will be used new way of identification and authentication based on eEHIC card.

8 Electronic prescription

Article 3 of the Act on Pharmaceuticals No. 378/2008 Coll., the Decree on Pharmaceuticals Prescribing Procedure, Data Indicated on Prescription and on Rules for Prescription Usage No. 54/2008 Coll. and the Decree on Correct Pharmaceutics Practices, Closer Conditions for Manipulation with Pharmaceuticals in Pharmacies, Healthcare Establishments and other Operators and Establishments Issuing Pharmaceuticals No. 84/2008 Coll. (vyhláška o správné lékárenské praxi, bližších podmínkách zacházení s léčivy v lékárnách, zdravotnických zařízeních a u dalších provozovatelů a zařízení vydávajících léčivé přípravky) contains requirements on process and content of prescription in paper and electronic form.

According to the Czech legislation it is possible to prescribe pharmaceuticals, other services, such as specialized medical care, are not operated under the scheme of prescribing (and electronic prescribing). Pharmaceuticals can be prescribed by physician providing healthcare (incl. dentist) and veterinarian. It is impossible to prescribe narcotics and psychotropic substances in electronic form.

Every prescription for human must be signed and dated by the physician. There must be also written identification of the patient (name, address, identification number for health insurance fund /in practice birth number/), health insurance fund of the patient (if the medicine is paid by insurance fund), name of the medicine (registered name, dosage, substance of the medicine), way of usage of the medicine, stamp with name of healthcare provider and name of the physician. In electronic form, the signature of the physician can be replaced by advanced electronic signature based on qualified certificate. The form of prescription (electronic/paper) that will be used is chosen after patient agrees on it.

Physician must send prescription in electronic form (it is XML form) to central repository (Electronic Prescription Central Repository that will be operated by the State Institute for Drug Control, Státní ústav pro kontrolu léčiv, http://www.sukl.cz/). Central repository sends back to the physician identification mark together with the electronic prescription. This identification mark is added to the prescription in the central repository. Communication between physician and central repository is encrypted and electronically signed. Identification mark has to be saved with the prescription in information system of the physician for later control. Physician must give identification mark to the patient. Patient will use the identification mark to get the medicine in the pharmacy.

Physicians can change data on the electronic prescription or cancel the electronic prescription until it has not been accessed by the pharmacist. The physician has access to all electronic prescriptions that he issued. The design of the system is prepared for implementation of other eHealth projects – it is planned that the patient will also have on-line access to all electronic prescriptions that was prescribed to him/her and can give identification marks of these prescriptions to any physician. This could minimize problems with prescription of incompatible medicine and prescription of similar medicine by more physicians.

If the prescription exists in electronic form, patient must have the identification mark to get it from the pharmacy. Pharmacist verifies if the prescription contains all required data and gives

the medicine to the patient. Pharmacist is obliged to send signed information on medicine release to the central repository. Communication between pharmacist and central repository is encrypted and electronically signed.
This all described in this chapter is possible according to existing law, but it will be practically useable after central repository will be operational – the Act on Pharmaceuticals left 1 year period for State Institute for Drug Control to establish it. Until 6 December 2008 it is not possible to use fully electronic form of prescriptions.
A patient is free to choose the healthcare provider. According to Act on Public Health Insurance, No. 48/1997 Coll. registering physician (general practitioner, dentist and gynecologist) sends recommendation to specialized physician. In the recommendation there is written reason and important health data. Registering physician recommends to the patient specialized physician and healthcare establishment, but the patient right to choose is not affected by this recommendation.

9 General assessment

The regulatory framework of the Czech Republic is not yet entirely ready for a full implementation of eHealth projects such as the exchange of patient's medical documentation and telemedicine but this situation is rapidly changing, because the eHealth strategy is going to be implemented. First success is legal possibility of electronic prescription.

There is still a problem with electronic identity management that has to be solved on a general level but it seems that it will also be solved soon and it seems that it will be possible to use the core of this system also in the health sector. There is a plan to use the eEHIC card for patient electronic identification, which will be specific for the health sector.

If there will be still enough pressure to realize planned projects, the Czech Republic could be very successful in the field of eHealth. After implementation of legislation there is needed also a second step – the realization of requirements established by the legislation. It is very important to design good applications for physicians that will be really helpful for them.

There is still a problem in the Czech Republic, that the penetration of internet connection among healthcare service providers is not as high as needed. But because usage of this form of reporting physician performances for health insurance funds is cheap and easiest (mainly for funds administration), this could support activities of health insurance funds (with internet services providers) in advantageous offer of internet connection.

For the development of cross-border eHealth services, the legal landscape of the Czech Republic contains no specific peculiarities. The transposition of the European data protection directive into Czech law follows quite closely the terminology of the Directive and no major additional requirements, compared to the EU Directive, have been added for the processing of personal data concerning health.

The system of electronic identification could be cross-border interoperable with solutions of other EU countries, because of usage of eEHIC card that is designed in coordination with the European project. Communication of information systems in health sector has to be cross border interoperable after modification of health data standards in the Czech Republic to be in conformance with HL7 standard.

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