

# SMART 2007/0059

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Study on Legal Framework of  
Interoperable eHealth in Europe

## **NATIONAL PROFILE ROMANIA**

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European Commission  
Directorate General Information Society

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

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	<p><a href="#">gp_survey_final_report.pdf</a>, Country profiles: <a href="http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm">http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm</a></p>
[RD9]	<p>Communication from the European Commission, “A Community framework on the application of patients' rights in cross-border healthcare”, 2 July, 2008, <a href="http://ec.europa.eu/health-eu/doc/com2008415_en.pdf">http://ec.europa.eu/health-eu/doc/com2008415_en.pdf</a></p>
[RD10]	<p>Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, <a href="http://ec.europa.eu/health-eu/doc/com2008414_en.pdf">http://ec.europa.eu/health-eu/doc/com2008414_en.pdf</a></p>
[RD11]	<p>European Commission, IDABC, eID interoperability for public government services (with country profiles): <a href="http://ec.europa.eu/idabc/en/document/6484/5938">http://ec.europa.eu/idabc/en/document/6484/5938</a></p>
[RD12]	<p>European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): <a href="http://ec.europa.eu/idabc/en/chapter/6000">http://ec.europa.eu/idabc/en/chapter/6000</a></p>
[RD13]	<p>Legally eHealth, Study on Legal and Regulatory Aspects of eHealth, <a href="http://www.ehma.org/projects/default.asp?NCID=140">http://www.ehma.org/projects/default.asp?NCID=140</a></p>
[RD14]	<p>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, <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML</a></p>
[RD15]	<p>Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, <a href="http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf">http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf</a></p>
[RD16]	<p>International Encyclopedia of Medical Law (editor: Herman Nys), <a href="http://www.ielaws.com/medical.htm">http://www.ielaws.com/medical.htm</a>, (with country monographs)</p>

## 2 Glossary

### 2.1 Definitions

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

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

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

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

**2.2 Acronyms**

<b>EHR</b> .....	Electronic Health Record
....	
<b>eID</b> .....	Electronic Identity
<b>eIDM</b>	Electronic Identity Management
.....	
<b>GP</b> .....	General Practitioner
...	
<b>HiT</b> .....	Health in Transition
.....	
<b>ICT</b> .....	Information and Communication Technology

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<b>MPH</b> .....	Ministry of Public Health
<b>NHI</b> .....	National Health Insurance Card
..	
<b>NHHI</b> .....	National House of Health Insurances
.....	
<b>OCSP</b> .....	Online Certificate Status Protocol
.....	
<b>PKI</b> .....	Public Key Infrastructure
....	
<b>PNC</b> .....	Personal Numeric Code
.....	
<b>TTP</b> .....	Trusted Third Party
.....	
<b>UIIS</b> .....	Unique Integrated Information System of Social Health Insurances

### 3 Introduction

#### 3.1 General overview of the Romanian healthcare system

An overview of the Romanian healthcare system can be found in the Romanian HiT country report published by the European Observatory on Health Systems and Policies <http://www.euro.who.int/document/e71423.pdf>, (87 p.) and in the September 2007 ERA Report “eHealth strategy and implementation activities in Romania” (Authors: Dezideriu Dan Farcas)

For our Study, the following observations, adapted and updated from the mentioned reports, are important:

The Romanian health care system was in a transition phase from a situation in which it was almost entirely state-owned and coordinated by the Ministry of Public Health (“MPH”) through 41 district health directorates and the Bucharest Health Directorate, towards a situation in which the relationships are more complex and the number of actors involved is bigger. At the moment, the main actors involved in the health care system are: MPH and the local public health authorities, the National and the local Houses of Health Insurances, the College of Physicians (hereinafter “College”).

MPH maintains the responsibility for developing national health policy and dealing with public health issues. The Ministry is responsible for the regulating and financing of the health insurance system; financing hospitals.

Until 1997, the main source of funding for the centralized health system was general revenues, mainly through the state budget. In the 1997, the Health Insurance Law transformed the Romanian health care system from a Semashko state financed model to an insurance based system. The law made insurance membership mandatory and linked it to employment; contributions depend on income and are paid in even shares by the insured and the employer. The Health Reform Law no. 95 of 2006 which provides the legal framework for the insurance system took over and continued the reform initiated by the 1997 Health Insurance Law, thus payroll contributions are the main sources of health sector funding. The state and local budgets are mainly sustaining health programmes and investments in buildings, equipment, endowment, while the health insurance covers mainly the healthcare services, and the pharmaceutical products reimbursement.

Patients are recommended to have a family physician and to notify him/her about changes in their health status. The citizens can freely choose their family physician but should stay with him/her at least six months before making the change. In order to have the hospital expenses reimbursed, the patient has to go to the hospital recommended by the family physician.

In the case of the family physicians the fees for patient consultations are paid by the local office of NHHI at the end of each month either for each insured person, per capita, or rendered to each medical service for the insured persons.

In case of hospitals, the fees are paid for each medical service. NHHI reimburses the treatment costs based on a notice from the family physician, or from any other specialized physician mentioning the recommendation for the patient to be treated in a hospital.

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NHHI reimburses all the costs of treatments and services included in the basic medical services package or in the minimal medical services package. The services included in the said insurance packages are provided in the Annex of April 1, 2008 of the Order issued by MPH concerning the Frame Agreement on 2008 regarding the Conditions for the Provision of Health Care.

The basic medical services package applies to all persons covered by social security. The minimal package is provided the persons who cannot prove they are insured, or are in situations like emergencies, epidemic diseases, pregnancy cases. There is also an optional, voluntary health insurance network, for complementary and supplementary services.

Health insurance covers ambulatory, inpatient, and dental care, including clinical preventive services and drugs. A framework contract, agreed upon annually by the National House of Health Insurances (“NHHI”) and the College and approved by the Romanian Government, defines the benefits package, conditions for service delivery, and payment mechanisms.

Pharmacies and pharmacists were among the first health facilities and health professionals that were privatized or allowed to operate their own private business. Pharmaceuticals can be prescribed by the healthcare providers, i.e. physicians and (to the extent that their profession requires) dentists and midwives. The pharmaceutical products are divided in three groups based on whether such products are reimbursed partly or fully. The reimbursable percentage of the cost varies depending on the therapeutic importance of the pharmaceutical.

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

There are no recent and reliable data on the use of ICT by Romanian specialists, hospitals or pharmacies. According to Order no. 607 of April 2, 2008 of the Health Ministry, every practitioner will receive a laptop and a printer. The Order was implemented starting with the end of April in almost all the counties. The physicians were not provided yet with a soft for creating and maintaining a patient data base, although according to the Health Reform Law all the data storage and transferring has to be operated using the Unique Integrated Informational System.

A recent (2007) report on the use of ICT by *general practitioners* in Romania which has been included in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe' (Empirica) presents some relevant data concerning the use on ICT in the Romanian health system. The study is available on Internet at:

[http://ec.europa.eu/information\\_society/eeurope/i2010/benchmarking/index\\_en.htm](http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm)

The Romanian country brief, presents the following key findings:

“In terms of infrastructure, 66% of the Romanian GP [General Practitioner] practices use a computer, which puts the country on a par with its European neighbours. However, only about half of those practices with a computer are connected to the Internet as well. In Romania, broadband connections have not yet arrived; they are used in only 5% of GP practices.

Romania displays its best eHealth performances in the area of patient data storage and use of a computer for consultation purposes. Yet even here the usage rates lie below the EU27

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average. Only half of the Romanian practices register administrative patient data and only about one-third of the GP practices store at least one type of medical electronic data.

In Romania, computers are used in consultation with the patients only to a very limited extent (22% of the practices). This percentage lies far behind the EU27 average of 66%.

Only 6% of the Romanian GP practices exchange medical data with other carers and only around 2% of the practices transfer administrative patient data to receive reimbursement via networked connections. The exchanged of medical data via networked connections is equally little established: only 2% of the GP practices participating in the survey reported having exchanged medical data with other health providers while 4% received results from laboratories this way.

ePrescribing is still not reality in most European member states. This holds true for Romania as well where none of the GPs having participated in the survey reported using ePrescribing.” The numbers above will change after the implementation of the Unique Integrated Informational System. Unfortunately the project started back in 2004, became operational in some counties, but not at a national level yet. By the end of 2008 the system should be operational at a national level.

### 3.3 National eHealth strategy

An overview of the Romanian eHealth policy can be found in the September 2007 ERA Report “eHealth strategy and implementation activities in Romania” (Authors: Dezideriu Dan Farcas): <http://www.ehealth-era.org/database/database.html#romania>

For our Study, the following observations, included in this Report, are important:

MPH is responsible for the health policy, regulations, health programmes, and investments in public health establishments.

The Health Reform Law requires the MPH to establish an information system for public health management. Other eHealth provisions in the same law relate to requirements for information on communicable diseases, emergency care, community assistance, hospital information, recognition of national Romanian health insurance cards.

The most important aspects of the Health Reform Law regard:

- The introduction of the National Health Insurance Card and also of the European card;
- Definitions of the civil liability of the medical personnel, and malpractice which means the professional error committed while exercising the medical or the medical and pharmaceutical acts, which cause damages to the patient, implying the civil liability of the medical personnel and of the provider of medical, sanitary and pharmaceutical products and services.
- The establishment of an integrated information system for public health management. MPH has a Strategic Plan for 2008-2010 underlining the necessity of a new integrated health services information system, which will include patient monitoring. The first steps for

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implementing such project were made at the beginning of 2008, when the MPH provided all the family doctors with technical support, i.e. laptops, printers.

In 2007, the MPH started a national evaluation programme, collecting health information on all citizens. All the data collected thereof, is expected to be included until the end of 2008, in an integrated, citizen oriented, public health management information system.

The National Health Insurance Card will be issued based on the collected data, starting with the second semester of 2008. This is an electronic card including a minimum of personal and health data, for use in emergencies and proving that the owner is insured in the social health insurance system of Romania.

Although a national health portal project was carried on by the Ministry of Communications and Information Technology in cooperation with MPH and with certain IT companies, due to the frequent changes in the management of both ministries, a relatively low priority for the portal update, as well as some administrative barriers stopped the proper updating of this portal.

A partial substitute for the public health portal are the sites of the MPH ([www.ms.ro](http://www.ms.ro), available in Romanian), of the NHHI (<http://www.cnas.ro/>, available in Romanian), and of the Romanian National Medicines Agency (<http://www.anm.ro/en/home.html>, available in Romanian and in English).

Most academic clinical hospitals are now members of a web community “mednet” (<http://www.mednet.ro/>, available in Romanian). Unfortunately a lot of medical web sites have disappeared for lack of funds.

One of the most recent e Health strategy proposed for Romania, elaborated in 2005, focused on interoperability of the information systems of the MPH with those of the public and private health insurance, of the health providers.

A general framework was proposed to be used first at a local level. It included, among other provisions, the main goals:

- to develop an integrated, unique, national, patient oriented health information system, including an electronic health record;
- to ensure the interoperability of the health information systems, and databases existing in Romania, as well as of the projects in progress;
- to offer real time decision support tools in the medical, economic and administrative fields;
- to issue a health card for each person;
- to identify patients and healthcare providers;
- to establish permanent data exchange mechanisms and processes among the main actors;
- to avoid unnecessary duplication or gaps in data collection.

In the Strategic Plan for 2008-2010, the MPH reaffirmed the importance and priority of the electronic health care services, underlining the necessity of a comprehensive, integrated health services information system, with patient monitoring, registers for non-communicable diseases. But so far no formal eHealth strategy or national roadmap is in force.

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As the Romanian health sector crisis deepened in the last years, the driving force in implementing e-health concepts and technologies is not the Ministry of Public Health but the Information Technology (IT) community, with a strong support from the Ministry of Information Technology and Communications and also from the Ministry of Education and Research, the Romanian Academy and professional non-governmental organizations. It is expected that IT will play an important role by improving the general health status of the population through a better management of health services and better access to information and knowledge, for both major actors: the health professionals and the citizens.

### 3.4 Regulatory framework for patients' summaries

Romania does not have legal provisions in the area of patients' summaries. However the Health Reform Law provides that the National Health Insurance Card, an electronic card, will provide at least a minimum set of information including the vital risk medical diagnoses; blood type and Rh. The first National Health Insurance Cards will be issued starting with second trimester of 2008 according to the information provided by the site of the Ministry of Public Health:

<http://www.ms.ro/index.php> (available in Romanian)

### 3.5 Regulatory framework for telemedicine

The Romanian legislation does not have specific provisions with regard to telemedicine. However the Health Reform Law refers to telemedical systems which are used for the transfer of data in emergency situations, without defining the concepts of telemedicine, telemedical systems and communications.

According to Art. 21 of the Professional Ethics Code of the Physicians (the "Ethics Code"), the physician may not treat a patient without personally examining him/her first. Only in exceptional cases, of emergency or force majeure (falling ill on sailing ships, flying planes, inaccessible places), treatment directions shall be given by telecommunications means. Although not regulated by the law, telemedicine has various directions of development in Romania, such as: data exchange in emergency situations, consulting and/or giving a second opinion.

There does not seem to be major legal obstacles to practice telemedicine in Romania. The legal literature about telemedicine in Romania refers mainly to the application of the Patient Law, the Data Protection Law and the medical secret. Also there is no jurisprudence in Romania with regard to the telemedicine.

### 3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions. According to the procedure for issuing a prescription, it is practically not possible to use electronic means to transmit a prescription. Electronic prescriptions are used mainly in hospitals mostly for administrative purposes. For more details we refer to Chapter 8 of this report.

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**3.7 Overview of relevant legislation**

The Health Reform Law unifies the legislation in the health area. The above-mentioned law, divided in seventeen titles, is the most important legislative source in this domain. The main topics of the law relate to:

- the development of national health projects concerning the evaluation, prevention and treatment of illnesses with a major impact upon the population;
- primary health care services, which refer also to the family physician;
- the national emergency healthcare system;
- communitary health care services;
- the national health insurance card and the European card;
- the legal conditions for practicing medicine;
- civil liability for health care personnel;
- drugs, special provisions regarding the production and trading of drugs.

The Health Reform Law also regulates the NHHI and refers also to the use of the unique integrated informational system.

Other provisions of the above mentioned law relate to the practice of health care, in particular the practice of medicine and to the liability for damages relating to health care provision. Of particular interest to eHealth are the laws regarding the protection of privacy in the context of personal data protection regulated by Law no. 677 of November 2001 on Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of Such Data and Law no. 46 of January 2003 on the Rights of Patients. Specific legal texts regulate the management of medical records (see further).

Also the laws concerning the Personal Numeric Code, the electronic identity card and the legislation regarding the electronic documents and electronic signatures (see Reference Documents under RD9 and RD10) are relevant.

## 4 Regulatory framework for the healthcare profession

### 4.1 Legal conditions for the practice of healthcare

In Romania, the regulations of the education system with regard to the professions in the healthcare sector are provided by the Health Reform Law no. 95 of 2006 and also by the Government's Decision no. 970 of 2004 transposing the Council Directive 93/16/EEC concerning the coordination of the provisions in respect of activities of doctors.

According to the Health Reform Law, the physician profession may be exercised, on the Romanian territory, by persons who have a diploma attesting the qualification as physician.

A diploma may be issued in the form of:

- a) a physician diploma, issued by an authorized medical and pharmaceutical higher education institution of Romania;
- b) a specialist physician certificate, issued by MPH;
- c) a physician diploma, certificate or medical degree issued by the states which are members of the European Union, of a state pertaining to the European Economic Space, or of Switzerland;
- d) a physician diploma, certificate or title acquired in a third state and recognized by one of the member states mentioned at paragraph (c) or attested in Romania;

In order to practice medicine, the physicians must be members of the College, and must have malpractice insurance. The certificate of member of the College is renewed annually.

The same rights and obligations as the Romanian physicians who are members of the College are provided for physicians who are citizens of a member state of the European Union, of a state pertaining to the European Economic Space, or of Switzerland, who are domiciled on the Romanian territory.

The scope of the physician profession is to ensure the state of health by prevention of diseases, promoting, maintaining and treating the state of health on both individual, and collective basis.

### 4.2 Control over the practice of medicine

Pursuant to the Health Reform Law, the monitoring and control of the exercise of the physician profession in Romania is carried out by the College and also MPH.

The College include Romanian physicians or physicians who are citizens of a member state of the European Union, of a state pertaining to the European Economic Space, or of Switzerland, domiciled in Romania. In accordance with the Health Reform Law, the physicians have the obligation to be registered with the College. The physicians who are citizens of a member state of the European Union, of a state pertaining to the European Economic Space, or of Switzerland have the same rights and obligations regarding the performance of their profession in Romania as the Romanian physicians.

The College establishes the strategy and the annual control and surveillance plan regarding the exercise of the physician profession and elaborates the Ethics Code, which provides for

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the rights and obligations of a physician, and the rules of legal professional conduct of the physician regarding its relationship with the patient.

The Ethics Code contains the rules concerning the medical activity conduct, the integrity and image of the physician, medical (professional) secrecy, the processing of health personal data, the transfer of medical data to other colleagues, and the relations between a physician and his/her patients, and with other colleagues.

The most important role of the College is to ensure the observance of the rules of professional conduct and the upholding of the reputation, standards of discretion, probity and dignity of its members.

### 4.3 Professional liability

The physician is liable in case of non-compliance with the laws and regulations regarding the physician profession, Ethics Code, the Statutes of the College, the mandatory decisions adopted by the management bodies of the College. The physicians may also be held liable for any acts or omissions committed in connection with the profession, which are likely to cause prejudice to the honour and prestige of the profession, or of the College.

Provisions with regard to the civil liability of the medical personnel are mentioned in Title XV of the Health Reform Law. Medical personnel includes the physician, dentist, pharmacist, nurse and midwife providing medical services. Malpractice is defined as the professional error committed while exercising the medical, or the medical and pharmaceutical act, which causes damages to the patient, causing the civil liability of the medical personnel and of the provider of medical, sanitary and pharmaceutical products and services.

The medical personnel is liable for the damages caused by error, including negligence, imprudence or insufficient medical knowledge while exercising the profession, by individual acts related to the prevention procedures, diagnosis or treatment. The medical personnel is liable for the damages deriving from the non-compliance with the regulations regarding the confidentiality, the consent, or the obligation to grant medical assistance.

Also, the medical personnel is liable for the damages caused while exercising the profession and when such exceeds the limits of competence, except for the emergency cases when no competent medical personnel is available.

In addition to the provisions of Health Reform Law, certain provisions of the Civil Code and Criminal Code may also be relevant with respect to the liability of physicians. Thus, Art. 998 – 999 of the Civil Code regulate the personal liability, and Art. 1000, paragraph 3 – the liability of the principals (the persons directing, guiding and controlling the activity of another person, employer) for the actions or omissions of the agent (the persons who have the obligation to follow guidance and directions received from the principals). Further, if an illegal act or omission violates the provisions of the Criminal Code, the physician will be held liable for the relevant crime(s).

The tort liability may be triggered if there is a connection between the tortious conduct of the physician and the injury of the patient.

The physician may act: as an employee, or as a private service provider on his/her own account. The differences between these situations are relevant for the nature of the contractual

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relationship with the patient and consequently also for the discussion about liability for damages.

In view of the fact that the characteristic of hospital medicine is that a patient is not confronted with one physician but with a medical team, the Health Reform Law provides that all the persons involved in a medical activity causing injury to a patient shall be liable on pro-rata basis according to the degree of fault of each person.

The Health Reform Law regulates two situations when the medical personnel is not held liable for the damages caused by the practice of medicine:

- when the medical personnel acts in good faith in emergency situations, within the limit of the granted competence;
- when the damages are caused by working conditions, the inadequate equipment, nosocomial infections, adverse reactions, generally accepted complications and risks of the methods of investigation and treatment, hidden faults of the sanitary materials.

A Commission (the “Commission”) was created for the purpose of investigating the malpractice cases. The Commission conducts investigations and issues decisions. In case any of the parties involved does not agree with the decision of the Commission, such party may challenge the said decision before the competent court, within 15 days of the date of the communication of the decision.

The legal action against a member of the College regarding acts related to the exercise of the physician profession may be filed after a prior notice was sent to the chapter of the College of which the respective physician is a member. The civil or criminal courts shall communicate, ex officio, to the College the final court’s decisions with regard to acts committed by physicians on the Romanian territory in connection with their profession.

### 4.4 Professional secrecy

One of the most important legal obligations of a physician, the professional secrecy, is regulated by the Health Reform Law, and also by the Ethics Code.

Article 14 of the Ethics Code lays upon the physician the obligation to not disclose confidential information concerning a patient of which he/she learns in the course of his/her professional practice, except for the cases provided for by the law.

All the information directly or indirectly made available to the physician, during the conduct of his/her profession, related to the private life of his/her patient, family, tutors, as well as all issues regarding the diagnosis, prognosis, treatment, various circumstances regarding the illness shall be regarded as a professional secret.

Pursuant to the provisions of the Ethics Code, the professional secret shall also be kept toward the tutors unless the patient wishes otherwise, and also toward the colleagues, medical personnel and medical institutions which are not involved in the medical act of the patient in question. The medical records shall be kept as secret professional materials.

In all scientific communications the cases shall be presented so that the identity of the patient shall not be recognized.

The Ethics Code also provides that in case that it is not contrary to the patient’s interests, the physician may allow the access of the media to the patient only with the consent of the latter.

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The head physicians of the medical units must take all the measures so that the access of the media to the patient is made only with the consent of the physician and of the patient. Article 196 of the Romanian Criminal Code provides that the disclosure of information by the person to whom the information was made available due to his/her profession is punishable with imprisonment or fine if it is likely to cause damages to the said person.

## 5 Processing of personal health data

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

The Romanian Law no. 677 on the Protection of Individuals with regard to the Processing of Personal Data and on the Free Movement of Such Data issued in November 2001 (hereinafter “Data Protection Law”), is transposing into national law the European Directive 95/46/EC. Therefore a parallelism between the Data Protection Law and the Directive is easily noticed.

The Data Protection Law transposed almost identically the provisions of the Directive on:

- the definitions of the essential concepts: personal data, processing, controller, processor, third party and recipient (Art. 2 of the Directive, Art. 3 of the Data Protection Law);
- the rules regarding data quality (Art. 6 of the Directive was transposed in Art. 4 of the Data Protection Law). The provisions on processing of personal data for scientific, historical or statistical purposes were enacted in Art. 12 (4) of the Data Protection Law;
- the criteria for making personal data processing legitimate (Art. 7 of the Directive Art. 5 of the Data Protection Law);
- the data subject’s rights to access, object, be the subject of automated individual decisions (Art. 12, 14 and 15 of the Directive, Art. 12, 15 and 17 of the Data Protection Law) although the Romanian legislation added specific provisions with regard to the said rights, i.e. for the right to access the health data (see further);
- the provisions with regard to confidentiality and security of processing (Art. 16-17 of the Directive, Art. 19 and 20 of the Data Protection Law);
- the notification of the processing to the data protection supervisory authority (Art. 18-19 of the Directive, Art. 21 and 22 of the Data Protection Law), though the Romanian law provides also the procedure of the supervision and control of the processing operations;
- the status and competences of the data protection supervisory authority (Art. 20, 21, 22 and 28 of the Directive: information on the Supervisory Authority For Personal Data Processing (the “Agency”) can be accessed at <http://www.dataprotection.ro/index.jsp?page=about&lang=en>).
- liability for damages as a result of unlawful processing (Art. 23 of the Directive), was transposed in Art. 18 of the Romanian law concerning the right to file a legal action;
- transfer of personal data to third countries (Art. 25-26 of the Directive, Art. 29-30 of the Data Protection Law).

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

With regard to the processing of special categories of personal data, i.e. transposition of Art. 8 of Directive 95/46/EC, the Data Protection Law contains distinct provisions for:

- a) Processing of special categories of data referring to all data mentioned in Art. 8 of the Directive, except the data concerning criminal convictions,
- b) Processing of health personal data, and
- c) Processing of personal data concerning criminal actions and offences.

Art. 7 of the Data Protection Law regulates the processing of data concerning health and reads as follows:

*“Art. 7 – (1) The processing of personal data revealing racial or ethnic origin, political, religious, philosophical or similar beliefs, trade-union membership, as well the processing of personal data regarding health or sex life is prohibited.*

*(2) The provisions of paragraph (1) shall not apply when:*

- a) the subject has given his/her express consent to such processing of data;*
- b) the processing is necessary for the purposes of carrying out of the obligations and specific rights of the controller<sup>1</sup> in the field of employment law (by complying with the guarantees provided by the law; a possible disclosure of the processed data to a third party may be performed only in case there is a legal obligation of the controller in such regard or if the person in question has given his/her express consent to such disclosure;*
- c) the processing is necessary to protect the life, physical integrity or health of the subject or of another person, in case the subject is physically or legally incapable of giving his/her consent;*
- d) the processing is carried out in the course of its legitimate activities by a foundation, association or any other non-profit organization with a political, philosophical, religious or trade-union purpose provided that the subject is a member of or has a regular contact with such organization related to its purposes and provided that the data shall not be disclosed to any third parties without the consent of the subject.*

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<sup>1</sup> Controller means the natural or legal person, public authority, agency or any other body which establishes the purposes and means of the processing of personal data;

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- e) *the processing refers to data which is manifestly made public by the subject;*
  - f) *the processing is necessary to ascertain, exercise or defend a right before the court;*
  - g) *the processing is necessary for purposes of preventive medicine, establishing medical diagnoses, provision of care or medical treatment for the subject or management of healthcare services to the subject's interest, provided that the processing of the said data shall be carried out by or under the supervision of a medical body subject to the professional secret or by or under the supervision of another person also subject to a similar obligation regarding the professional secret.*
  - h) *the law expressly provides this for reasons of protection of an important public interest, provided that the processing of data shall be carried out in compliance with the rights of the subject and of the other guarantees provide by this law.*

*(3) The provisions of paragraph (2) do not infringe on the legal provisions which regulate the obligation of the public authorities to comply with and protect private and family life.*

*(4) The supervision authority may prohibit, for justified reasons, the carrying out of a data processing mentioned at paragraph (1) even in case the subject has given his/her written and unequivocal consent, and such consent was not withdrawn, provided that the interdiction mentioned at paragraph (1) shall not be obviated by any of the cases to which paragraph (2) b) – g) refers to.”*

The processing of health personal data is also regulated in Art. 9 of the Data Protection Law, which provides the following:

*“Art. 9 – Except for the cases mentioned at Art. 7(2), the provisions of Art. 7 (1) shall not apply with regard to the processing of health data in the following cases:*

- a) the processing is necessary for the protection of public health;*
- b) the processing is necessary in order to prevent an imminent danger, the committing of a criminal act or in order to prevent the occurrence of the damages as a result of such act.*

*(2) The processing of health data may be carried out only by or under the supervision of a medical body, only in compliance with the professional secret, except for the case when the subject has given his/her written and unequivocal consent as long as such consent was not withdrawn, as well as except for the case when the processing is necessary in order to prevent*

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*an imminent danger the committing of a criminal act or the occurrence of the result of such act or the damages as a result of such act.*

*(3) Medical bodies, health institutions and their medical personnel may process health personal data, without the authorization of the supervision authority, only if such processing is necessary for the protection of the life, physical integrity or health of the subject. When the above-mentioned purposes refer to other persons or to the general public and the subject did not give his/her written and unequivocal consent, the prior authorization of the supervision authority must be obtained. The processing of personal data beyond the limits mentioned in the authorization is prohibited.*

*(4) Except for emergency reasons, the authorization mentioned at paragraph (3) may be granted only after the College of Physicians has been consulted.*

*(5) The health personal data may be obtained only from the subject. By exception, such data may be obtained from other sources only in case such is necessary in order not to compromise the processing purposes, and the subject cannot or does not wish to provide these data.”*

With regard to the provisions of Art. 7 and 9 of the Data Protection Law, the following comments can be made:

- The Romanian law does not provide a definition of personal data concerning health. In absence of such a definition, the following definition of the Council of Europe recommendations regarding the processing of health data will apply: “*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.*”
- As mentioned above, the written consent of the data subject is required when processing personal data concerning health on the basis of the consent of the data subject. According to Law no. 455 of 2001 on Electronic Signature “writing” also includes electronic means used by the data subject to express his/her will. However, at this time, the electronic signature is only exceptionally used in Romania.

### **5.3 Information and access rights of data subjects**

Art. 13 of the Data Protection Law provides that any person has the right to obtain a confirmation as to whether the data related to him/her is being processed by the controller upon filing an application. The controller must communicate the requested information within 15 days as of the date of receipt of the application.

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With regard to the health personal data, the application mentioned above may be submitted by the subject either personally, or by a member of the medical profession who will indicate in the application the person on whose behalf the application is submitted. At the request of the controller or of the subject, the communication can be made to a member of the medical profession appointed by the subject.

The Data Protection Law also provides that *“in case the health personal data is processed for scientific purposes, in case apparently there is no risk to infringe on the rights of the subject and if the data is not used in order to take decisions or measures toward a certain person, the communication can also be made within a period exceeding 15 days, if such could affect the carrying out or the results of the research, but no later than the moment the research has finished. In such case, the subject must have given his/her express and unequivocal consent to the processing of the data for scientific purposes, as well as to the possible delay of the communication for such reason.”*

**5.4 Other relevant rules regarding personal data protection**

The Data Protection Law provides that the Agency shall keep a register of the personal data processing. Each controller shall be granted a registration number, which further on shall be mentioned on each document whereby the data is collected, stored and disclosed. The said register shall be available for the public.

## **6 Rights and duties of healthcare providers and patients**

The rights and duties of healthcare providers and patients are enacted in the Law no. 46 on the Rights of Patients of January 2, 2003 (hereinafter “Romanian Patient’s Rights Law”), in the Health Reform Law and in the Ethics Code.

### **6.1 Scope of the law**

According to the Patient’s Rights Law, “patient means the healthy or ill person to whom healthcare services are provided”. The law does not provide a definition of the term healthcare services. However, the Health Reform Law provides the obligations of the healthcare providers, which refer to promoting, determining, preserving, improving the patient’s state of health or in order to support a dying patient. Following this definition, acts such as removing an organ from a donor, terminating a pregnancy, etc. do not constitute healthcare. Moreover, medical experiments involving persons are not covered by the law’s domain of application. Health professionals in the current state of the legislation are: physicians, dentists, midwives, pharmacists, physiotherapists, nurses, paramedics and nurse assistants. Practitioners of non-conventional medicine (Law of 29 April 1999) are also considered as health professionals.

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

The duty of the patient to co-operate is not provided by the Romanian law. The only practical legal meaning would seem that a health professional who is sued by a patient, may seek a defense by arguing that a patient did not co-operate.

### **6.3 Right to quality care**

As provided by Art. 2 of the Patient’s Rights Law, the patients are entitled to the highest quality medical care the society can provide in accordance with financial, material and human resources available.

### **6.4 Right to free choice**

According to Art. 49 of the Ethics Code, the physician shall respect the patient’s right to freely choose his health professional, and even to facilitate the possibility of such a choice.

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

The patient has the right to be informed with regard to the available medical services and how to use such services, and with regard to the identity and the professional status of the health service providers.

According to the Patient’s Rights Law, the patient has the right to be informed with regard to his/her health state, the suggested medical interventions, the potential risks of each procedure, the alternatives to the suggested procedures, the diagnosis and the prognosis and the consequences of not undergoing the treatment and failing to comply with the medical

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recommendations. The patient has the right to ask and receive a written brief including the above-mentioned information.

The patient has the right to decide whether he/she still wishes to be informed in case the information provided by the physician would cause him/her suffering. The patient has the right to expressly request not to be informed and to choose another person who shall be informed instead.

The patient is informed respectfully, by using a minimum number of medical terms; in case the patient does not speak Romanian, he/she shall be informed in his/her mother tongue or in a language he/she is familiar with or, as the case may be, another form of communication shall be resorted to.

In case the disclosure of an unfavorable prognosis may affect the patient, or in case the patient does not want to be informed with regard to the prognosis, such prognosis may be disclosed to the family.

**6.6 Right to give consent**

The consent of the patient is necessary for any diagnosed or therapeutic medical intervention and shall be expressed as provided by the law.

The consent shall be given after the patient has been informed with regard to the diagnosis, prognosis, therapeutic alternatives, including the risks and benefits thereof.

In the case of underage or incompetent patients, or of those who cannot express their will, the consent shall be given by their legal representatives. If the physician believes that the decision of the legal representative is not in the patient's interest, a professional arbitration committee shall be set up in order to examine the case and take a decision.

In emergency cases, when the life of the patient is in jeopardy, and the latter cannot express his/her will and his/her relatives or legal representatives cannot be contacted, the consent is implicit, and the physicians shall make all the efforts to save the patient, who will be informed afterwards.

The patient has the right to consent well informed, freely and in advance to any service provided by a health professional. The consent is only valid for the medical intervention consented to. 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; The consent has to be recorded and added to the medical record at the patient's or the professional's request and with the health professional's or patient's approval. The information to be given to the patient prior to the consent is specified in the law. Patients have the right to refuse or withdraw consent for any service.

**6.7 Rights related to the patient's medical record**

The patient has the right to a medical record which will be updated and stored by the health professional. Every health professional should keep a medical record about every patient to whom he/she provides healthcare services.

The National Archive Law no. 16 of 1996 (hereinafter "National Archive Law") includes provisions with regard to medical records. The mentioned law specifies the storage conditions

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for the documents. Also according to the National Archive Law, the medical records should be archived for a period of 30 years. The law also provides for the conditions according to which the deceased patient's medical record may be consulted.

According to Order no. 1782 of 2006 on Registration and Statistics Reports of Patients who Receive Healthcare Services in Hospitals on a Continuing Basis or per Day, the use of the General Health Record was approved and it is used since January 2007 for all the hospitalized patients on a continuing basis. The said order also refers to the Daily Health Record which is used when the patient is hospitalized per day.

The order explicitly states that the medical records are to be kept both in paper and in electronic format. The order also contains precise rules with regard to the content of the General Health Record and Daily Health Record. The General Health Record needs to be signed by the physician(s) who provided care to the patient, while the Daily Health Record bears the code of the physician's seal.

Hospitals should archive the records of all patients who left the service, preferably in a central database or at least per service and in an electronic format with a unique number per patient. The archive should be accessible to physicians who are involved in the provision of care to the patient.

According to the Romanian Patient's Rights Law, the patient has access to his/her personal medical data and the confidential information may be disclosed only in case the patient gives his/her explicit consent or if the law expressly provides that.

Although electronic medical records were used in some Romanian hospitals since 1985, so far a unified collection of data about the health history of every person is not available. Currently, the Health Evaluation Programme which was started by MPH in July 2007 collects health data on all the Romanian citizens and it is expected to provide a national database by the end of December 2008.

**6.8 Right to protection of privacy and intimacy**

All information regarding the condition of the patient, the results of the check-ups, the diagnosis, the prognosis, the treatment, and the personal data is confidential even after the death of the patient. The confidential information may be disclosed only in case the patient gives his/her explicit consent or if the law expressly provides that.

Any interference in the private family life of the patient is prohibited, except for the cases when such interference may influence the diagnosis, treatment, or health care in a positive way, and only with the consent of the patient. Exceptions represent the cases when the patient may be regarded as a danger to himself/herself, or to public health.

With regard to the right to protection of intimacy, the Ethics Code provides that the physician involved in research shall promote and protect the life, intimacy and dignity of the subjects participating in the research. The legislation in the health area does not include an explicit provision with regard to the protection of the right to intimacy for all the patients, but such right arises from the regulations regarding the protection of privacy, i.e. the Patient Law, the Ethics Code.

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**6.9 Right to representation in case of incompetence**

The Patient's Rights Law, the Health Reform Law and the Ethics Code do not contain explicit rules regarding the right to representation in case of incompetence of a patient, who is legally or factually not capable of exercising his/her rights as patient.

For such situations the general civil rules apply. Therefore in the case of minor patients, if the minor is under 14, his rights are exercised by the parents or by the patient's guardians. If the minor patient reached the age of 14, he will be able to exercise his rights, bearing in mind his age and level of maturity.

## 7 Identity management in the health sector

A general identity management system for the Romanian healthcare sector including the identities of patients, and healthcare professionals is not yet available. However, once the National Health Insurance Cards will be issued, i.e. by the end of 2008, all the information provided by such electronic card will form the first national database which will include health information on every citizen. The information in this chapter is based on the IDABC-report referenced under [RD9] on Romania and on the e-health-era report referenced under [RD4].

### 7.1 Overview

In Romania the records of natural persons are held by the National Inspectorate of Personal Records ([www.evidentapersoanelor.ro](http://www.evidentapersoanelor.ro), available in Romanian) and the National Center of Administration of the Databases Regarding Personal Records. In Romania, until the age of 14 the main identity document is the birth certificate. After the age of 14, an ID Card is issued for each natural person. Currently a project regarding the establishment of an electronic system is implemented, although the eIDM systems are not yet properly operating in Romania and the electronic ID cards have not been issued yet. By January 1, 2009 the issuance of the Electronic ID cards will be initiated.

The electronic ID cards will be issued after the implementation of the project for the establishing of a unique web portal of the local public administration, which will serve for the authentication, and permission to access of the citizens to the websites of the authorities providing e-government services. Another project that has not been implemented yet regards the establishing of a connection between the National IT System of Public Records, and other IT systems of the local public administration.

According to the National Center of Administration of the Databases Regarding Personal Records, the electronic ID card will provide, in addition to the information regarding the current identity card, data regarding the civil status, voting right, the medical and social insurance, biometrical identification data and proof of the electronic signature.

When completed and operational, the system should allow the access to the personal records of all the authorities, and institutions whose competences require such actions and which will be authorised in respect thereof.

The main identification data is the Personal Numeric Code (“PNC”), a 13 digit ID number, containing the gender, date of birth, place of birth and some other data. The said personal numeric code is included among the data available on the identity card, and will also be included on the electronic ID card and on the National Health Insurance Card.

Identification information with regard to legal persons is primarily stored by the Trade Registries, and are coordinated at central level by the National Office of the Trade Registry. The database of the National Office of the Trade Registry is also available online, based on a subscription. The companies are identified by the Trade Registry Number, and by the Sole Registered Code.

## 7.2 The NHI Card

The National Health Insurance Card is an electronic card identifying patients, and healthcare providers, providing that the owner is insured in the social health system of Romania and containing minimum personal and health data, for use in emergencies, therefore contains both health data and health insurance data. The cost of this card is borne by the health insurance fund. Although the issuance of this card began at the end of 2007, it was postponed for 2008. According to Art. 331 of the Health Reform Law, the minimum information which can be provided on the NHI card is the following:

- a) identity data and personal numeric code;
- b) proof re the payment of the contribution for the health insurance;
- c) registration of the number of medical services requests, through the code of the provider;
- d) vital risk medical diagnoses;
- e) blood type and Rh;
- f) expiry date of the card;
- g) identification number and the acronym of the health insurance house issuing the card;
- h) card number;

The card will also include the consent to donate tissues and organs.

The NHI card will be issued by the health insurance house where the owner of the card is registered, only via the integrated unique information system of health insurance.

In accordance with the provisions of the Health Reform Law, the NHI card can be used only on the Romanian territory.

For the Romanian citizens staying temporarily abroad in EU countries, (i.e. less than 6 months), a European health insurance card may be issued. This non-electronic document can be used to obtain reimbursement for some medical services rendered abroad.

## 7.3 Unique Integrated Information System of Social Health Insurances (UIIS)

An equivalent of the Belgium Crossroads Bank for Social Security does not exist in Romania. The Unique Integrated Information System of Social Health Insurances (“UIIS”) may be used by all institutions working with the Social Health Insurance System: the NHHI, the County Houses of Health Insurance, the medical and pharmaceutical service suppliers.

UIIS has components for finance, accounts, investments, inventory, purchase, payroll, human resources. The elimination of double registered insured persons or double reporting of services, quick statistical reports, better monitoring and control of the resources, elimination waiting times are expected to be among the benefits of the implementation of such system. According to the Health Reform Law, UIIS will be used also used for the issuance of the national insurance card.

So far, UIIS was used in some counties, but it is not yet operational at a national level.

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**7.4 Patient identifier**

The identification of the citizen is based on his Personal Numeric Code (hereinafter “PNC”), which is a 13 digit ID number, containing the gender, date of birth, place of birth and some other data. PNC was introduced back in 1978. For more than 20 years it is currently available and defined for practically all Romanian citizens, including patients, physicians, dentists, pharmacists. It is included in passports, ID cards, population databases; it is used also for elections, banking, and insurances. The PNC is used in hospitals and it will also be included in the national insurance card.

According to Art. 6 of the Ordinance no. 97 of 2005 on the Domicile, Residence and Other Identification Documents of Romanian Citizens, the PNC represents the sole identify code for all the informatics systems which process personal data with regard to the natural persons.

**7.5 Authentication of healthcare professionals**

According to the Health Reform Law, one of the conditions to practice medicine is to be a member of the College. The College is in charge with setting up and updating of the Physicians Sole Register, which, according to the said law, will be also available on the web site of the College (<http://cmr.ro/>, available in Romanian). So far, these provisions of the law have not been yet implemented.

According to an Order of the Ministry of Public Health no. 1059 issued in 2003, the Sanitary Statistics and Medical Research Center (*Centrul de Statistica Sanitara si Documentare Medicala*) (hereinafter “SSMRC”) shall set up and update the National Physicians Register. This register contains information about the diploma and the specialization of the healthcare provider, which is identified through his stamp number and also through his PNC. SSMRC provides the stamp numbers which are granted to physicians. The stamp number is confidential and is granted to each physician by the Territorial Public Health Authority upon the express request of the physician. According to the above-mentioned order, the stamp number cannot be object of a statistics report and represents the physician identifier in relation to all the medical documents.

**7.6 Exchange of health-related data**

The exchange of health-related data at a national level is to be made by using the UIIS. The project was set up by the NHHI and has a hardware and basic software endowment component. From a technical-organisational perspective, the UIIS has an important role in the creation and the management of the national health database.

Upon the implementation, according to the representatives of the NHHI, UIIS will be a performant tool, flexible and compatible with other similar European systems, which will ensure a total transparency and also an efficient check up of all healthcare and pharmaceutical services provided to patients.

By using UIIS, a preventive control on the legitimacy of the access to the information regarding a patient, and also the possibility of automatic communication of information to certain health care providers will be achieved.

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The health data will be collected by the physicians for each patient and will include the medical check-up card, prescriptions, medical leave, and will be transmitted at the end of each month to the Local House of Health Insurance by using the Special Telecommunications Service (STS).

STS is the central specialized structure, which organizes and coordinates the telecommunications operations of the public authorities in Romania and of other users as provided by the law.

By the end of this year, all the health-related data exchanges are to be made on-line using the internet. The online transmission is not yet possible as not all the healthcare providers have all the necessary equipment.

From a legal perspective, all the procedures and operations, and every transmission of health-related data through the UIIS will be in compliance to the provisions of the Data Protection Law. A special authorization procedure is required for the transfer abroad of such personal data. When UIIS becomes nationally operational, the detailed procedure of the transfer of health-related data will be provided by MPH and the NHHI.

## 8 Electronic prescription

The medical prescriptions are regulated by the Health Reform Law and by orders issued by the MPH and the President of the NHHI.

Order no. 832/302/2008 of the Ministry of Public Health and the President of NHHI regulates the authorization of the model of the medical prescription application. According to the Methodological Norms regarding the Use and Methods of the Filling In of Medical Prescription Applications with Special Regime with Regard to Medicines (hereinafter “the Norms”) which implement the above-mentioned Order, every prescription shall be signed and dated by the physician, and shall be stamped with the stamp which will include the physician code.

In an annex to the Norms, a model of the prescription document is provided. Pursuant to the Norms, the medical prescription shall include, among other data:

- the diagnosis – means all the patient’s diagnoses with regard to which medicines with or without personal contributions were prescribed;
- the date of the prescription – means the date of the issuance of the medical prescription;
- the physician’s signature (stamp/code) – means the signature of the physician who issued the prescription and the corresponding stamp and code thereof;
- the prescribed medicines.

Further on, the Norms provide that the medical prescriptions with or without personal contributions shall be printed on auto copy paper in 3 colours. The 3rd page (green) shall remain with the notebook of the physician who prescribed the medicines, while the 1st page (white), and the 2nd page (pink) shall be submitted to the insurance holder, who will submit them to the medicine supplier. The medicine supplier shall keep the pink page, while the white one (the original) shall be filed with the NHHI together with the invoice and the centralization registers.

The patient is free to choose the healthcare provider. The Norms provide that the medical prescription may be issued by any pharmacy which, upon the date of the issuance of the medical prescription, has concluded a contract with the NHHI regarding the supply of medicines.

According to Art. 39 of the Ethics Code, the physician may not advertise any medicines or consumption medical products. Moreover Art. 42 provides that it is prohibited for the physician to get involved in the distribution of any authorized or unauthorized remedies, medical equipment, or products.

The Health Reform Law regulates the procedure for the issuance of prescriptions. The NHHI reimburses in part or entirely to the pharmacies the cost of drugs prescribed by the physicians, as it is established in the framework contract.

In Romania, computerized procedures for prescription (transmission of prescriptions) are used mainly in hospitals, between physicians and internal pharmacies, for administrative purposes. Also the IT applications for pharmacies outside the hospitals are made by private companies and used mainly for the stock management or for reimbursements from the Health Insurance.

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## **9 General assessment**

Although the Romanian regulatory framework might be ready for the implementation of eHealth projects such as the exchange of patient's summaries, telemedicine or electronic prescriptions, Romania lacks technological resources. The first steps in order to fulfil this request were taken at the beginning of 2008, though the project started back in 2005.

The health insurance system is operational but still needs to be improved. All efforts invested in the health projects should materialize by the end of 2008, when the first national health database will be operational. This database will include the health data collected from all the citizens based on a national evaluation programme, which started in July 2007, and will end in 2008. All the data collected thereof, is expected to be included until the end of 2008 in an integrated, citizen oriented, public health management information system.

Also 2008, will be the year when the first national health insurance electronic cards are issued. The national health insurance card will be the first card to be issued in Romania to also provide electronic information. The projects regarding the issuance of an electronic ID card are expected to start beginning with 2009.

Although not available at national level, e-health applications are flourishing. The main local applications refer to hospital information systems (HIS), electronic health records (EHR), image processing, diagnosis and treatment aids, teleradiology, teleconsultation, education, research and domain oriented web support services.

The most important achievement in the ehealth area will be the set up of a national network and infrastructure which will connect health care providers, health insurance houses, patients. Such infrastructure and networks will be operational at a national level in the next couple of years and will be used in large-scale eHealth projects in various fields, including patients' summaries, telemedicine and electronic prescriptions. The development of such projects will probably lead also to the update of the legal framework in the health area

The Romanian legislation on data protection transposed the European data protection directive by following the terminology of the Directive. The Data Protection Law added detailed provisions with regard to the processing of personal data concerning health.

Corina Papuzu  
12 June 2008

## Annex: Contact details of National Correspondents

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