

SMART 2007/0059

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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE BULGARIA

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European Commission
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1 Documents

1.1 Applicable Documents

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

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/200807_02-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/europe/i2010/docs/benchmarking/

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	gp_survey_final_report.pdf , Country profiles: http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
[RD9]	Communication from the European Commission, “A Community framework on the application of patients' rights in cross-border healthcare”, 2 July, 2008, http://ec.europa.eu/health-eu/doc/com2008415_en.pdf
[RD10]	Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, http://ec.europa.eu/health-eu/doc/com2008414_en.pdf
[RD11]	European Commission, IDABC, eID interoperability for public government services (with country profiles): http://ec.europa.eu/idabc/en/document/6484/5938
[RD12]	European Commission, IDABC, eSig-Web (Electronic signatures applications in public government services – country overviews): http://ec.europa.eu/idabc/en/chapter/6000
[RD13]	Legally eHealth, Study on Legal and Regulatory Aspects of eHealth, http://www.ehma.org/projects/default.asp?NCID=140
[RD14]	Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:EN:HTML
[RD15]	Article 29 Data Protection Working Party, Working Document on the processing of personal data relating to health in electronic health records (EHR), WP 131, http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2007/wp131_en.pdf
[RD16]	International Encyclopedia of Medical Law (editor: Herman Nys), http://www.ielaws.com/medical.htm , (with country monographs)

2 Glossary

2.1 Definitions

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

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

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

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

2.2 Acronyms

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

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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 Bulgarian healthcare system

A comprehensive and recently updated (2007) overview of the Bulgarian healthcare system can be found in the Bulgarian HiT country report published by the European Observatory on Health Systems and Policies (written by Lidia Georgieva, Petko Salchev, Rostislava Dimitrova, Antoniya Dimova and Olga Avdeeva).

<http://www.euro.who.int/Document/E90023.pdf> (178 p.).

From the executive summary of this report, the following important observations could be mentioned:

“The sociopolitical changes that have taken place in Bulgaria since 1989 have had a big impact on the health system. The previous “Semashko” model was based on the principles of universal coverage and free access at the point of delivery. The system was centrally planned and run, financed from general government revenue and characterized by almost complete public ownership. It is also notable that there was an absence of a private sector (as the private system was abolished) and that all professionals in the health system had the status of salaried civil servants.”

“Major reforms began in 1989 and by the mid-1990s they had transformed the centralized, tax-based system into a decentralized and pluralistic compulsory health insurance system, with employee contributions and contractual relationships between the National Health Insurance Fund (NHIF) as a purchaser and health care providers.”

“Privatization is another important feature of the Bulgarian health system. The Health Care Establishments Act outlined procedures for the privatization of both state and municipality medical establishments. Private practice was legalized in 1991 and has since expanded significantly, and in 1992 ownership of most health care facilities was devolved to locally elected municipalities.”

“The main sources of health system financing are compulsory health insurance, state and municipality budgets, voluntary health insurance (VHI), household expenditure allocated to the system as co-payments, fee for service or out-of-pocket expenses, and external resources allocated from donor organizations and national and international nongovernmental organizations (NGOs).”

“At the time of writing, inpatient care is financed from three sources: government budgets, municipal budgets and health insurance. The NHIF pays only to contracted hospitals per case or clinical pathway consisting of a number of diagnoses, with fixed prices. Hospitals which have not contracted with the NHIF continue to be paid by the municipalities or by the State. Hospitals also receive additional revenue from compulsory co-payments and fees for those services that are not covered by the basic benefits package of health insurance.”

“The compulsory health insurance guarantees a basic benefits package to the insured population, defined by the National Framework Contract.”

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The compulsory health insurance contribution is 6% of a monthly wage divided according to a 60:40 ratio between the employer and employee for the year 2008, and set to reach 50:50 in 2010.

“Physicians working in the inpatient sector are salaried. Providers of outpatient care are contracted with the NHIF and are paid by fee-for-service. Physicians in primary care are reimbursed per capita and reimbursement depends on the number of patients on the physician list.”

“Reimbursement to general practitioners is based on per-capita monthly payments per insured person on the patient list. Specialized outpatient care and laboratories are reimbursed by means of a fixed fee for services provided to patients. Dental care is mostly paid out of pocket, based on fee-for-service, although a limited number of dental services are included in the basic benefits package.”

“The health reform relies to a great extent on the creation of a new actor in outpatient care: the general practitioner. General practitioners act as gatekeepers to specialized and hospital care, thus reducing expenditure on costly healthcare. The reforms created new types of outpatient institutions that embrace single and group practices, medical and dental centres and independent medical diagnostic centres.”

3.2 Use of ICT in the Bulgarian healthcare sector

There are no recent and reliable data on the use of ICT by Bulgarian specialists, hospitals or pharmacies. A recent (2007) status of the use of ICT by *general practitioners* in Bulgaria 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 Bulgarian country brief, we take over the following key findings:

“In terms of infrastructure, 97% of the Bulgarian GP practices use a computer, which puts the country on a par with 13 other EU countries where a computer availability rate of nearly 100% is reached. Only 47% of Bulgarian GP practices are connected to the Internet, a result which is below the EU27 average of 69%. Broadband connection has not yet arrived in Bulgaria; only 23% of the Bulgarian GP practices make use of it.

Electronic patient data storage is quite common in Bulgaria. At least one type of individual data is stored in 96% of GP practices. The results reached in Bulgaria for the storage of the different types of medical patient information (e.g. diagnoses, medications etc.) are all above the European averages.

A computer is available in the consultation room in 86% of the Bulgarian GP practices.”

“In Bulgaria 76% of the GPs – e.g. nearly all GPs that have a computer in the consultation room - actually use the computer for consultation purposes with the patient. This corresponds to a quite low availability versus use gap.

55% of the Bulgarian GP practices use a Decision Support System for diagnosis or prescription purposes (50% on average in the EU27).

The electronic exchange of patient data on the other hand is not yet well established. This concerns medical as well as administrative patient data. Only 5% of the GP practices receive

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results from laboratories. This compares to an EU27 average of 40%. The reception of lab results is the type of medical patient data exchange the most frequently used. Only 3% of the Bulgarian GP practices exchange medical data with other health care providers. In this regard as well Bulgaria positions itself below the EU average of 10%.

6% of the Bulgarian GPs exchange administrative data with other care providers, compared to the average rate of 10% reached by the EU27. With a usage rate of 10% for the exchange of administrative data with reimbursers, Bulgaria scores slightly below the EU average of 15%. The electronic exchange of prescriptions, commonly referred to as ePrescribing, is practiced by only 2% of the GP practices in Bulgaria.“

3.3 National eHealth strategy

An overview of the Bulgarian eHealth policy can be found in the March 2007 ERA Report “eHealth strategy and implementation activities in Bulgaria” (Author: Alexander Ognianov):

http://www.ehealth-era.org/database/documents/ERA_Reports/Bulgaria_country_report_final_07-03-2007.pdf

For our Study, the following observations, adapted and updated from this report, are important:

The major goal of the Strategy for the Introduction of Electronic Healthcare in Bulgaria is to transform the healthcare system so that it becomes convenient for citizens through the planned intensive introduction of ICT. The objectives of the Strategy are improvement in the health status and quality of life of Bulgarian citizens, by providing equal access to advanced, effective health services of high quality, through the utilization of new and existing technological means, in accordance with the evolving necessities and increased mobility of population and establishment of an information structure that will allow the introduction of citizen-oriented health services.

For realization of the strategy is necessary to be fulfilled operational goals like improving the quality of health services for the citizens, orientation of the healthcare model fully towards the end-user, providing full and objective information for all medical and financial activities, providing more complete medical information to the healthcare specialists, creation and usage of telemedical infrastructures, ensuring possibility for effective communication between health specialists, facilitating the access to health information, engaging nongovernmental organizations and the IT sector for realization of the strategy, development of integrated information environment.

The most important issues which have to be addressed by the legal regulations are the following:

- Proofreading and revision of the specific legal regulation of the healthcare, which will allow the usage of information and communication technologies and enable the transition from the "paper" to the electronic world with the subsequent validity of issued actions and documents;

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-
- Defining particular rules providing high and overall information protection;
 - Defining the obligations of each participant in the health system in accordance with the business model.

An inseparable part of the aforementioned Strategy for implementation of electronic healthcare in Bulgaria is the 2007-2013 Action Plan. The Plan's working version has been developed in the end of 2006. Based on the performed analysis and a study on the experience of other countries, several priority basic projects have been defined. A crucial part of the Action Plan is the establishment of an adequate business model and legal regulation in the healthcare sector.

The pilot projects, listed below, have been started in 2007 in accordance with the Strategy. Since the projects have not yet been fully implemented, the concepts for their implementation are described.¹

1. Electronic Medical Records - Creating of Electronic Medical Records for 20 000 Bulgarian citizens in a pilot region in Bulgaria. The Medical Record must contain the patient's personal information, medical information from the citizen's contact with and visits to different medical facilities, as well as information about those facilities.

The accumulated information will be structured and organized in the database in such a way that the different sections - administrative, passport, medical and financial to be logically split and in this way free access from anyone to the personal data stored in the centre would be rendered impossible.

It is also planned to store information needed in emergency, life-threatening states of the patients. This information will contain a medical part: chronic diseases, allergies, medications, immunizations, blood group and blood transfusion, operations, family history and others. The administrative part is also very important and will contain contacts of treating physicians, specialists - any health officer engaged with the particular patient. This information could be accessed not only by emergency units, but also by other organizations, as the check for data access is done by special procedures, that prove the needed permissions.

The data in the centres will be accessed (also by the patients) through a specific portal or using special card readers and secured encrypted connection. The respective users will have read and write access to a predefined information level, using special mechanisms for protection of the delivered information.

2. Electronic Health Cards - introduction of electronic health cards for patients and doctors that will contain medical and administrative information.

Main data that will be stored, accessed and processed through the electronic health cards, according to European best practices are:

¹ The information concerning the pilot e-Health projects is amended and supplemented with recent information.

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- Administrative data - including passport data of the patient, patient's photo, gender, insurance status, financial coverage;
 - Medical data – information, concerning emergency medical assistance, blood group, allergies, risk factors, medications, vaccinations, implants available, electronically issued prescriptions, past and current illnesses, transplantations, data for the pregnant women, living will of the patient concerning organ donation.

In the end of 2006 a pilot project for the introduction of eHealth cards in Slivnitsa has been introduced. The project includes the following basic components.

Electronic cards:

- Electronic professional cards of GPs and pharmacists;
- Electronic health cards of patients.

Specialized software:

- Specialized software for GPs for identification, electronic prescriptions, etc.
- Specialized software for pharmacists for identification and the processing of Electronic prescriptions.
- Databases and applications, processing electronic prescriptions, patients lists of GPs, and information about NHIF contract partners.

Specialized hardware: Card readers, communication devices. Communication devices provide the means for encryption of information and apply existing protection and data transfer standards (including XML, HL7).

The pilot project includes 7 GPs, 5 pharmacies and 1,000 patients.

“In the event of a patient visiting their GP, both of them identify themselves through their electronic cards. The health insurance status of the patient, his belonging to the patients list, etc., are verified. In case of validation, the doctor resumes his/her medical work, entering the required information. On the basis of the reached diagnosis, the doctor would be able to generate an electronic prescription, which then would be stored in a server. The prescription would be stored and kept in the patient's health card until the moment of its realization. The patient would visit a pharmacy that can apply such an identification procedure. The action is reflected in the electronic prescriptions server, where its status is changed to "executed" or the like, it is registered in the pharmacist's software program and is deleted from the patient's electronic health card.”

3. Health Portals

The proposed strategy plans the development of health portals that facilitate the access to the health information. For this purpose it is needed to fully guarantee the protection of the personal health information from unauthorized access.

A pilot project for creating National electronic health portal and creating and integrating of personal electronic health records of 40 000 officials of the state administration is in process of implementation.

The concept is each citizen to have online access to the National Health Portal and to personal health webpage (web-profile) containing information of his/her health status. The National

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Health Portal also must ensure possibility for communication between the medical specialists and to provide information about hospitals, hospital wards, etc.

The access to the data is planned to be allowed by using electronic signatures.

4. Telemedicine services

The building of a telemedicine infrastructure and real development of projects for remote access treatment is also outlined in the Strategy.

The realization of telemedical projects is to work on the principle of continuous expansion of the system span. This means to start with a pilot project that includes one or several hospitals and their related infrastructures and, from this point on, to enlarge the system in different stages, until it becomes a national one, covering all belonging infrastructures.

3.4 Regulatory framework for patients' summaries

Bulgaria doesn't have legal provisions in the area of patients' summaries. It is planned to introduce the patients' summaries as one of the four main part of the Electronic Health Records (Electronic Medical Records). As was mentioned above in 2007 started pilot project for creating Electronic Health Records of 20 000 citizens.

3.5 Regulatory framework for telemedicine

There are no specific provisions in Bulgaria with regard to telemedicine. Several main legal obstacles to practice telemedicine in Bulgaria can be outlined. Adequate regulatory framework with respect to the processing and access to medical data and the shared medical secret is necessary to be adopted. The provisions of health insurance legislation are not adapted to the needs of the telemedicine and the compulsory health insurance does not cover telemedicine services. However, pursuant to Art. 82, Para. 2 Bulgarian Health Insurance Act (*Закон за здравното осигуряване, HIA*) the provision of health services or products that are not covered by the compulsory health insurance may be covered by the voluntary health insurance.

We did not found any jurisprudence in Bulgaria with regard to the provision of medical advice to patients by telephone.

3.6 Regulatory framework for electronic prescriptions

Under the Bulgarian legislation at the present moment the prescription of medical products is regulated in the Medicines in the Human Medicine Act (*Закон за лекарствените продукти в хуманната медицина, МНМА*) and the Ordinance № 4 from 15th January 2001 for the Conditions and the Order for Prescription and Issue of Medicinal Products (*Наредба № от 15 януари 2001 г. за условията и реда за предписване и отпускане на лекарствени продукти, Ordinance No 4*).

According to the Ordinance No 4 the prescription of medical products should be made in writing, on a paper medium, on an approved by the Minister of Healthcare form. For this reason the use of electronic means for prescribing pharmaceuticals is not allowed.

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3.7 Overview of relevant legislation

The legal framework regarding health policy in Bulgaria encompasses a number of normative acts, the most important of which are: the Health Act (*Закон за здравето*, HA, promulgated in the State Gazette, issue 70 from 2004), the Health Insurance Act (*Закон за здравното осигуряване*, HIA, promulgated in the State Gazette, issue 56 from 1998), the Medical Establishments Act (*Закон за здравните заведения*, MEA, promulgated in the State Gazette, issue 62 from 1999), Medicines in the Human Medicine Act (*Закон за лекарствените продукти в хуманната медицина*, MHMA, promulgated in the State Gazette, issue 31 from 2007), Blood, Blood Donation and Blood Transfusion Act (*Закон за кръвта, кръводаряването и кръвопреливането*, BBDBTA, promulgated in the State Gazette, issue 102 from 2003), Organ, Tissue and Cell Transplantation Act (*Закон за трансплантация на органи, тъкани и клетки*, OTCTA, promulgated in the State Gazette, issue 83 from 2003), Medical Products Act (*Закон за медицинските изделия*, MPA, promulgated in the State Gazette, issue 46 from 2007).

They govern various public relations in the area of healthcare – protecting public health, health insurance, the management and activities of medical establishments, guidelines for use and registration of medicines, blood donation, blood taking and diagnostics, transplantation procedures, procedures on launching medical products on the market and their subsequent operation. Other aspects on healthcare in Bulgaria are included in provisions of various normative acts. Analysis of these normative acts shows that there is no consistent and comprehensive regulation of electronic healthcare in Bulgarian legislation. The current legal framework cannot adequately regulate public relations in the area of healthcare in the climate of high technologies.

On 13th June 2008 the new Bulgarian Electronic Governance Act (*Закон за електронното управление*, EGA, promulgated in the State Gazette, issue 46 from 12th June 2007) as well as four of the secondary acts for its implementation – the Ordinance for the Registers of the Information Objects and of the Electronic Services (*Наредба за регистрите на информационните обекти и на електронните услуги*, ORIOES, promulgated in the State Gazette, issue 48 from 23rd May 2008), the Ordinance for the Internal Circulation of Electronic Documents and Paper Documents in the Administrations (*Наредба за вътрешния оборот на електронни документи и документи на хартиен носител в администрациите*, OICEDPDA, promulgated in the State Gazette, issue 48 from 23rd May 2008), the Ordinance for the Electronic Administrative Services (*Наредба за електронните административни услуги*, OEAS, promulgated in the State Gazette, issue 48 from 23rd May 2008), the Ordinance for the Certificates for Electronic Signatures in the Administrations (*Наредба за удостоверенията за електронен подпис в администрациите*, OCESA, promulgated in the State Gazette, issue 48 from 23rd May 2008). The rest of the secondary legislative acts for the implementation of EGA – concerning the information security and the interoperability of the information systems of the administrations and the creation of integral environment for document exchange - will be also adopted and promulgated in the nearest future.

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In accordance to EGA the state and municipal medical establishments as well as the organizations, which provide health services, shall provides their administrative services and internal administrative services (i.e. administrative services provided to the administrative bodies, persons with public functions and organizations, providing services for satisfying public needs) in electronic way, unless the law provides for special form for performing of some actions or for issuance of the respective acts. Thus, after appropriate amendment of the current health legislation the provision of some e-Health services will be not only possible, but compulsory.

It should be mentioned that according to Art. 7 of EGA the Minister of Healthcare shall issue ordinances to regulate particular aspects of provision of services in the healthcare sector and to specify particular standards, formats and requirements for exchange of medical data and electronic documents.

Of particular interest to eHealth is the Personal Data Protection Act (*Закон за защита на личните данни*, PDPA, in force as of 1st January 2002) in the context of personal data protection. Also relevant is the Electronic Document and Electronic Signature Act (*Закон за електронния документ и електронния подпис*, EDESA, in force as of 6th October 2001) and the laws regulating the provision of information society services and the consumer protection.

4 Regulatory framework for the healthcare profession

4.1 Legal conditions for the practice of healthcare

The regulation of the education leading to the various professions in the healthcare sector in Bulgaria is a competence of the Bulgarian National Assembly, the Council of Ministers, the National Agency for Evaluation and Accreditation at the Council of Ministers, the Minister of the Education and Science and the Minister of Healthcare. The educational programs are generally adapted to the European requirements in this area. The rules for acquiring degree in the system of the healthcare are regulated by a special ordinance, adopted by the Council of Ministers.

In accordance with Art. 175 of the HA healing arts comprise medicine, dentistry, when practiced on human beings, pharmacy in both their curative and preventive aspects. The education of the nurses and midwives is also kind of medical education, but they perform their profession only together and under the control of physicians or dentists. 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. It is also all-embracing, which means that it covers every activity that has to be considered as belonging to medicine. An exception has been made for dentistry: generally speaking physicians are not allowed to practice dentistry.

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

- Possession of the legally required diploma: a procedure for recognition of the diplomas awarded in other EU Member States is in place.
- A registration at the regional body of the Bulgarian Medical Association competent for the place in which the physician intends to practice.

The activities, which belong to the field of medicine when they have the purported purpose, in respect of a human being, are:

- Diagnostics, medical treatment and rehabilitation of patients
- Supervision of pregnant women and provision of childbirth's aid;
- Supervision of patients with chronic diseases or persons in danger of disease;
- Prophylactic of diseases and early detection of diseases;
- Measures for strengthening and protection of the health;
- Transplantations of organs, tissues and cells;

Preventive medicine belongs to the legal monopoly of physicians. The specialized medical tests may be also performed by physician or under the supervision of a physician. 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 actions performed by the nurses may be performed only 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

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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 Bulgaria is supervised by number of state bodies. Bodies of the state health control are the general state health inspector of the Republic of Bulgaria, the regional inspectorates of public health protection and inspection and the National Center for Radiobiology and Radiation Protection (Art. 12 of HA). The state health control is performed by state health inspectors at the above mentioned bodies. Competent to control the observation of the code of professional ethics of the physicians and the rules of the good medical practice is the Commission for Professional Ethics at the Bulgarian Medical Association² and the respective Commissions for Professional Ethics at the regional bodies of the Bulgarian Medical Association (Art. 16, Para 2 and Art. 28 of the Professional Organizations of the Physicians and the Dentists Act, POPDA, *Закон за съсловните организации на лекарите и лекарите по дентална медицина*, promulgated in the State Gazette, issue 83 from 1998). The Commissions for Professional Ethics at the regional bodies supervise the observation of the professional-medical, moral-ethic and deontological issues related to the practice of medical profession, examine complaints and ascertain malpractices, issues recommendations for their suspension and inflict sanctions.

The code of professional ethics, adopted by the Bulgarian Medical Association, contains the rules concerning the individual relations between the physician and the patient, relations between the physicians, medical secrecy, handing over of medical data to colleagues, remuneration of the physician and the role of the physician in the society. The code further formulates the principles on the basis of which the social obligations of the physicians are determined and can further state which clauses are forbidden in agreements between physicians and other parties, when these clauses are not compatible to the principles of professional ethics and more specifically to the therapeutic freedom of physicians.

4.3 Professional liability

The professional liability of a physician is, with the exception of the liability for observing the ethic rules and the good medical practices under POPDA, currently not governed by special laws in Bulgaria. However, HA contains special provisions for administrative liability of the physicians for infringement of certain obligations stipulated by the law – like providing information to the patient, obtaining the informed consent of the patient, etc.

The civil 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 law. Civil liability of a physician may arise when an obligation is not fulfilled and damages are caused. However, at this stage problems of proving medical malpractice action impede the realization of the civil liability of the physicians.

² The official website of the Bulgarian Medical Association - <http://blsbg.com/?cat=home>.

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Regarding the criminal liability, the Bulgarian Criminal Code (*Наказателен кодекс*, CC, in force as of 1 May 1968) contains number of special provisions concerning crimes committed by physicians when performing their professional functions. The grounds criminal liability to arise are negligence, incompetence, performance of medical activities in a state of intoxication, infringement of the rules for acting as a physician, forced abortion, refuse to render medical aid to a patient, issuance of false medical documents, revealing etc.

4.4 Professional secrecy

One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician. Article 145 of the Criminal Code lays upon each person a legal obligation not to disclose information which he learns in the course of his professional practice and which can danger for someone's good reputation.

In particular, this provision applies to physician with respect to the professional secrecy of the information acquired directly from the patient, as well as information concerning the patient, which the physician learns from other sources. According to Art. 51 of the code of professional ethics the physician shall not reveal such information to the members of the patient's family. The medical secrecy covers not only information but also the entire medical documentation, illustrative materials, conclusions and consultations. Furthermore, the secrecy over the information confided by the patient stands even after his/her death.

Two main exceptions from the medical secrecy are determined in the code of professional ethics. First, when more than one physician treat one patient (simultaneously or consecutively) they are not bound by the professional secrecy between them, unless in case of motivated refuse of the patient (Art. 53). Second, in cases, where special obligation for providing information to certain institution is established by the law, the physician is not obliged to keep medical secrecy (Art. 55).

Article 145 of the Criminal Code has a large field of application and not only applies to physicians alone but to everyone who, in the course of his professional practice, is being informed of information which can danger someone's good reputation. Therefore, not only physicians but also nursing and paramedical personnel are bound to a duty of secrecy. However, the rules of the code of professional ethics concerning the medical secrecy are applicable only to physicians.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 2002 Bulgaria has general legislation protecting the individual with regard to automatic processing of personal data. The Personal Data Protection Act (*Закон за защита на личните данни*, PDPA, in force as of 1 January 2002) has been amended numerous times in order to transpose the provisions of the European Directive 95/46/EC.

Generally speaking the Bulgarian Personal Data Protection Act is very similar to the European directive. The Bulgarian legislator has been very reluctant to make a maximum use of his possibilities to specify or to further detail the provisions of the Directive. Therefore there is almost literal parallelism between the Bulgarian law and the Directive with regard to:

- the definitions of the essential concepts: personal data, processing, controller, processor, third party, recipient and consent (art. 2 of the Directive);
- the rules regarding data quality (art. 6 of the Directive);
- the criteria for making personal data processing legitimate (art. 7 of the Directive);
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject's rights (art. 12, 14 and 15 of the Directive);
- the provisions with regard to confidentiality and security of processing, but the Bulgarian legislator provides that the general rules shall apply even to the processing operations concerning public security, defence, State security and the activities of the State in areas of criminal law, unless otherwise provided for in a special law (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive);
- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Bulgarian Personal Data Protection Commission can be read at <http://www.cpdp.bg/>).
- transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

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

As far as the processing of special categories of personal data is concerned (transposition of art. 8 of Directive 95/46/EC) the Bulgarian law contains one general provision for sensitive personal data, including the data concerning health.

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Art. 5 of the Bulgarian law regulates the processing of data concerning health and is formulated as follows:

“Art. 5. (1) It is forbidden the processing of personal data, that:

1. reveal revealing racial or ethnic origin;
2. reveal political opinions, religious or philosophical beliefs, memberships in political parties or organizations, associations with religious, philosophical, political or trade-union purposes;
3. concern health, sex life or human genome.

(2) Paragraph 1 shall not apply where:

1. processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law;
2. the data subject has given his explicit consent to the processing of those data, except where special law provides otherwise;
3. processing is necessary to protect the life and the health of the data subject, who these data concern, or other natural person and his/her status does not allow him/her to give his/her consent or other legal obstacles are in place;
4. processing is carried out in the course of its legitimate activities with appropriate guarantees by a non-profit-seeking organization, including with a political, philosophical, religious or trade-union aim and on condition that:
 - a/ the processing relates solely to the members of this organization or to persons who have regular contact with it in connection with its purposes;
 - b/ the data are not disclosed to a third party without the consent of the data subject who concern.
5. the processing relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims;
6. processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, where those data are processed by a health professional subject under the law to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

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7. processing is carried out solely for journalistic purposes or the purpose of artistic or literary expression as far as it does not violate the right to privacy of the data subject who these data concern.”

The following comments can be made with regard to art. 5 of the Bulgarian law and other relevant provisions:

- Personal data concerning health is not further defined in PDPA. Pursuant to Art. 27, Para 1 of the Health Act (HA), health information shall be regarded any personal data that is connected to the state of health, the physical and mental growth of the persons as well as any other information which is included in medical prescriptions, protocols, certificates and in other medical documentation.
- It is disputable in the Bulgarian doctrine whether the term "personal data concerning health" has more wide meaning than the health information.
- Processing personal data concerning health on the basis of the consent of the data subject is only possible if the controller has obtained a explicit consent, which means that it is not necessarily “writing”. However, for purposes of eventual dispute or claim the controller shall prove the consent of the data subject.
- According to Art. 27, Para. 2 of HA health information could be processed, collected, used and stored by medical and health establishments, Regional Healthcare Centres, regional inspectorates for protection and control of the public health, physicians, dentists, pharmacists and other medical professionals as well as non-medical professionals with higher non-medical education working in the national healthcare system.
- The data subject can provide a written consent for processing personal data concerning health without the supervision of a healthcare professional. Provided that the purpose of the legislator was to generally prohibit the health information from disclosure it would have been explicitly stipulated. This conclusion is based on the Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Presently, there is no explicit prohibition in a special law which is reason to consider that health information can be processed by non medical professionals if the consent of the data subject is given. However, this information shall be accessible only to people who are authorized by the respective data subject.
- All persons who have access to the health-related data need to be subject to a legal or equivalent contractual duty of confidentiality with regard to the data concerned.
- As a matter of principle, personal data concerning health should always be collected directly from the patient. This rule has been taken over from the Council of Europe Recommendation.

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5.3 Information and access rights of data subjects

PDPA does not contain special rules for information and access rights of the data subject when data concerning his/her health is processed, i.e. the data subject have right to information and access under the general rules for information and access rights to personal data. On the other hand, Art. 86 of HA stipulated that the patient has right to clear and intelligible information for his/her state of health and the methods of his/her eventual treatment.

The treating physician is obliged to inform the patient regarding his/her state of health and the necessity of treatment, the disease which is reason for seeking for medical aid and his/her prognosis, the planned prophylactic, diagnostic, treating and rehabilitative activities and the risks related to them, the diagnostic and therapeutic alternatives and the names, positions and specialities of the persons involved in the diagnostic-treating process (Art. 92 of HA). The access of the patient to the health information concerning the disease which is reason for seeking for medical aid and his/her prognosis and the planned prophylactic, diagnostic, treating and rehabilitative activities and the risks related to them may be restricted in case of his/her written denial but this is necessary to be entered into the medical documentation.

5.4 Other relevant rules regarding personal data protection

Other relevant rules regarding personal data concerning health are related to the activities of the labour medicine offices which are competent to render assistant to the employers for creating organization for safety and health during work, to assess the professional risks and to analyse the state of health of the employees, to propose measures for elimination and decrease of the risk, to supervise the state of health of the employees, etc. They are subject to registration at the Ministry of Healthcare. Physicians at these offices perform periodical examinations of the employees and keep health information. It is important to be indicated that the employers under the Bulgarian law does not have right to collect and store health information about their employees. Thus, the labour medicine offices perform a kind of intermediary role between the employer and employees.

Furthermore under Art. 28 of HA health information may be transferred by the persons under Art. 27, Para 2 of HA (see above) to third parties only for exhaustive number of purposes:

1. when the treatment of the patient continue in other medical establishment;
2. when there is a danger for the health or life of other persons;
3. when it is necessary for identification of human corpse or for finding the reasons for the death;
4. when it is necessary for the needs of the state health control for prevention of epidemics and dissemination of infectious diseases;
5. when it is necessary for the needs of the medical expertise and social insurance;
6. when it is necessary for the needs of the medical statistics and for medical scientific examinations after the data is depersonalized;
7. when it is necessary for the needs of certain state authorities in the healthcare system which are exhaustive listed in the law.

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The persons under Art. 27, Para 2 are subject to an obligation to ensure the protection of the health information stored by them against unauthorized access.

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the Bulgarian Health Act and the code of professional ethics of the Bulgarian Medical Association.

6.1 Scope of the law

Patient means "the natural person who seeks or to whom medical aid is rendered" but the law does not explicitly defines the meaning of the term "medical aid" (Art. 84 of HA). However, detailed regulation of the activities falling within the "medical aid" is provided in special provision for the different kind of medical establishments and practices. Special rights of the donors of organs, tissues and cells are stipulated in a special law (see above). The registration of one natural person as a patient shall be with his/her informed consent, except the cases determined by the law.

6.2 Duty of the patient to co-operate

Pursuant to Art. 94 of HA the patient shall co-operate of the persons providing medical aid when they perform activities for improvement or recuperation of his/her health. Other obligations of the patient fixed in the law are to take care for his/her own health, to not harm the health of the others and to observe the rules of the medical and health establishments.

6.3 Right to quality care

High quality care entails care in accordance with the prevailing standards as determined by the current state of science. The patient has right to accessible and quality medical aid.

6.4 Right to free choice

The patient's right to free choice is restricted with respect to choosing general practitioners who have contracts with the NHIF. He may choose only one general practitioner and can change his choice only twice for one year. The access of the patient to specialist in different area of the medicine is also restricted in the system of the compulsory health insurance since it is necessary direction from his GP.

6.5 Rights related to information about the state of health

A patient has the right to receive from the health professional all relevant information necessary to assess his state of health and his prognosis. Communication with the patient must take place in clear and intelligible way. In certain cases like for example histological intervention or other risky treating methods the provision of this information shall be written. Information about the disease which is reason for seeking for medical aid and his/her prognosis and the planned prophylactic, diagnostic, treating and rehabilitative activities and the risks related to them is not provided to the patient if the latter explicitly requests not to know. The explicit request not to know must be given in writing and has to be noted in the medical record.

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6.6 Right to give consent

The medical activities may be performed after the expressed informed consent of the patient. 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 of the patient. 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. Medical aid against the patient's will may be rendered only in cases determined by the law.

6.7 Rights related to the patient's medical record

Every physician should keep a medical record about every patient to whom he provides healthcare services according to the code of professional ethics. One ordinance of the Ministry of Healthcare from 2006 determines the content of the medical records. However, the regulation of this issue is not enough well organized and gaps have been identified. Generally, most of the provisions in the Bulgarian legislation concerning the patient's medical record are related to the reporting of the provided medical services, which are financed by the compulsory health insurance. There is not prohibition the medical record to be kept in electronic form. Furthermore, the reporting of the provided medical services shall be made electronically.

6.8 Right to protection of privacy and intimacy

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health. They have also a right to the protection of their intimacy. It is forbidden the physician to use the examination for intimate contact with the patient.

6.9 Right to representation in case of incompetence

HA 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 (over 14 years). In such cases is necessary his consent along with the consent of his parents or guardians.

7 Identity management in the health sector

A co-ordinated identity management system for the Bulgarian healthcare sector including the identities of patients, healthcare professionals and other stakeholders is not yet available.

7.1 Overview

The prevalent eIDM system in Bulgaria is based on the Bulgarian Unique Identifier (Unified Citizen Number for the Bulgarian citizens, Personal Number of the foreign citizens on the territory of the Republic of Bulgaria, Unified Identification Code of the companies and BULSTAT Code of other kind of entities). Although most of these identifiers exists from long time, the concept of this coordinated eIDM system is very new and was introduced by EGA. With this regard it is still not completely implemented in the practice. The idea is the above mentioned identifiers to be use for identification of the respective person before all institutions, persons with public functions and organization providing services for satisfaction of public needs. The information about the persons is kept in respective official registers – natural persons in the Unified System for Civil Registration and Administrative Service of the Population (<http://www.grao.bg/esgraon.html>); commercial companies and sole traders in the Commercial Register (<http://www.brra.bg/>), BULSTAT register for other entities (<http://www.registryagency.bg/bg/Services/bulstat/f226.html>). Information about the companies which are not reregistered in the new Commercial Register is still kept also in the old Commercial Registers at the District Courts.

7.2 Identification Management in the health insurance system

The Identification management of the insured natural persons in the compulsory health insurance system is based on the above mentioned identifiers. Each GP receive a list of the persons whose health insurance rights are suspended. Furthermore, the patients have to identify themselves before their GP with their health books, which at this stage are on paper. On the health books the Unified Citizen Number of the person is printed along with other personal data. Information about the current GP of the person is also entered in this document. The health book is used for identification before the medical establishments as well as before the dentists in the compulsory insurance health system. This document is not required for the provision of medical services which will not be reimbursed by NHIF. In practice, because of the above mentioned lists of the persons whit suspended health insurance rights the health books are not always required by the physicians.

7.3 Authentication of healthcare professionals

Physicians and respectively dentist are registered in the register their professional associations. The publicly available register part of the Bulgarian Medical Association contains information about the name and the place (region) where the physician perform its activities. This register is available on the Bulgarian Medical Association website (<http://blsbg.com/?cat=32>).

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The medical establishments, the labour medicine offices and of the pharmacies are subject to registration at the Ministry of Healthcare. These registers, as well as other registers related to the healthcare in Bulgaria are available on the website of the Ministry of Healthcare (http://www.mh.government.bg/6_registers/41_hospital/).

7.4 Exchange of health-related data

At this stage the exchange of health related data is not well regulated. The most important step with this regard is that from the beginning of 2008 the reporting of the provided medical services to authorities in the system of the compulsory health insurance is performed electronically. In fact all stakeholders (healthcare professionals and medical establishment) were obliged to report electronically. For the purposes of this reporting the use of universal electronic signature (i.e. qualified electronic signature, issued by certification-service-provider registered at the Bulgarian Communication Regulation Commission) is mandatory.

8 Electronic prescription

Under the current Bulgarian regulation of the prescription of medical products stipulated in MHMA and Ordinance № 4 the prescription of medical products should be made in writing, on a paper medium, on an approved by the Minister of Healthcare form. With this regard the use of electronic means for prescribing pharmaceuticals is not allowed. The competent authority to determine the method of prescription of pharmaceuticals is the Minister of Healthcare. In this respect the conditions and order for prescription of medical products in an electronic form should be regulated by an Ordinance of the Minister of Healthcare. However electronic prescriptions are issued within the eHealth pilot project implemented in Silistra (see above).

9 General assessment

The Bulgarian regulatory framework is not yet ready for a full implementation of eHealth projects such as the exchange of patient's summaries, telemedicine or electronic prescriptions. The few pilot eHealth projects which started in 2007 in Bulgaria have presented comprehensive illustration of the complete lack of adequate legislation in this field.

Furthermore, presently there are no draft legislative acts in this area.

However, one extremely important and revolutionary act which will benefit the development of the eHealth in Bulgaria is already fact – the new Electronic Governance Act, as well as the secondary legislation for its implementation. The future special legislation will follow the common principles and policies adopted in the current e-governance legislation. We expect that the obligations of the stakeholders in system of healthcare which have been introduced by EGA will speed up the development of the eHealth in Bulgaria. The implementation of EGA will probably lead to the adaptation of the legal framework in the field of healthcare and of the Bulgarian eHealth Strategy.

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