

# SMART 2007/0059

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Study on Legal Framework of  
Interoperable eHealth in Europe

## **NATIONAL PROFILE GREECE**

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European Commission  
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Brussels

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**1 Documents**

**1. Applicable Documents**

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

**2. Reference Documents**

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 <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

### 3. Definitions

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

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

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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.

**2.1 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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<b>HiT</b> .....	Health in Transition
.....	
<b>OCSP</b> .....	Online Certificate Status Protocol
<b>PKI</b> .....	Public Key Infrastructure
....	
<b>NRN</b> .....	National Register Number
..	
<b>SIS</b> .....	Social (security) Information System
.	
<b>SSCD</b> .....	Secure Signature Creation Device
<b>SSIN</b> .....	Social Security Identification Number
....	
<b>TTP</b> .....	Trusted Third Party



### 3 Introduction

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

An overview of the Greek healthcare system can be found in the County Report for Greece that was prepared in the frame of the eHealth ERA project (2007) [1] and the report on Highlights on health in Greece prepared by the World Health Organisation (2004) [2]. In this part we will reproduce important observations and we will complement them with more information based on other sources.

The Greek health care system is characterised by the coexistence of the National Health Service (NHS), a compulsory social insurance and a voluntary private health insurance system. The NHS provides universal coverage to the population through approximately 210 health centres, 1400 health posts and 110 hospitals and operates on the principles of equity, equal access to health services for all and social solidarity. In addition, 97% of the population is covered by approximately 35 different social insurance funds (compulsory social insurance), whereas 8% of the population maintains complementary voluntary health insurance coverage bought on the private insurance market [2].

Suppliers of health care services are the broader Public Sector (Hospitals in the National Health System or hospitals with some other public character, health centres and regional surgeries, insurance fund and municipal surgeries, etc.) and the pure Private Sector (private hospitals and clinics, diagnostic centres, doctor's and dentist's clinics, etc.). Furthermore, healthcare is also provided by the Greek Social Security Organisation (IKA), which operates approximately 300 primary health care units in various regions of Greece and 5 main hospitals (4 of which can be found in Athens and one in Thessaloniki) [1].

The Ministry of Health and Social Solidarity (renamed from "Ministry of Health and Welfare" in March 2004) decides on overall health policy issues and on the national strategy for health. It sets priorities at the national level, defines the extent of funding for proposed activities and allocates resources. Since 2001, 17 Regional Health Systems (R.H.S.) have been established, originally named P.E.S.Y.P. (Regional System of Health and Welfare) and currently referred to as D.Y.P.E. (Regional Health Administration). Law 3527/2007 reduced the number of D.Y.P.E. from 17 to 7; the realisation of this reduction has still not been completed<sup>1</sup>. These Regional Health Systems are given extensive responsibilities for implementing national priorities at the regional level, coordinating regional activities and organising and managing the delivery of health care and welfare services within their catchment area. Decentralisation efforts have consisted mainly of devolving political and operational authority to regional authorities but stopped short of shifting full financial responsibility to them to the extent that the Regional Health Systems were not given individual budgets to manage and the Ministry itself still has to validate all financial transactions [2].

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<sup>1</sup> A list of the currently existing D.Y.P.E. can be found at <http://www.mohaw.gr/gr/ygeia/links/allpesyp>

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The Greek health care services are organised in terms of the services provided. Four such services are distinguished [3]:

- Primary health care.
- Secondary and tertiary health care.
- Emergency health care.
- Psychiatric health care.

All services are publicly and privately supplied with the exception of the emergency health care, which is publicly provided only [3].

Primary health care in the public sector is delivered through primary health care centres (particularly in the rural areas), as well as through the outpatient services of NHS hospitals and the primary care units belonging to the largest social fund, IKA. Health care centres provide also emergency services, short-stay hospitalization and follow-up treatment for recovering patients, dental treatment, family planning services, preventive health, vaccinations and health education. The National Health System is responsible for the provision of hospital, emergency pre-hospital and primary healthcare services on a universal basis. [4].

Out of the total 132 NHS hospitals, those with capacities between 100-200 beds provide primarily secondary care services to their respective populations, while the 32 hospitals with a capacity of over 400 beds provide tertiary and highly specialized care. Outside the NHS, there are 13 Military Hospitals financed through the Ministry of Defence, 5 Hospitals of the Greek Social Security Organisation (IKA), financed by the social fund and two teaching hospitals under the authority of the National Kapodistrian University of Athens [4].

The private sector offers hospital level services (primarily through general and maternity hospitals making up for almost 26% of total hospital bed capacity in the country) and primary care services through private practices, laboratories and diagnostic centres. These services are remunerated on a fee-for-service basis either through contracts with social insurance funds or directly by patients themselves. Dental care, rehabilitation services and services for the elderly are for the largest part offered through the private sector [4].

Health services in Greece are funded almost equally through public and private sources. Public expenditure is financed by both taxes (direct and indirect) and compulsory health insurance contributions (by employers and insured people). Voluntary payments by individuals or employers represent a very high percentage of total health expenditure (more than 42% in 2002), making Greece's health care system one of the most "privatized" among the European Union countries. In 2002, Greece's expenditure on health amounted to 9.5% of GDP, of which an extremely high 4.5% accounted for private health expenditure (47% of total expenditure) [2].

It is interesting to point out that according to the OECD [5] there are more physicians per capita in Greece than in any other OECD country. During the past decades, the number of doctors per capita increased rapidly in Greece to reach 5 practising physicians per 1.000 inhabitants in 2005, well above the OECD average of 3.1. On the other hand, there were only 3.3 nurses per 1.000 inhabitants in Greece in 2005, a much lower figure than the average of 9.7 in OECD countries.

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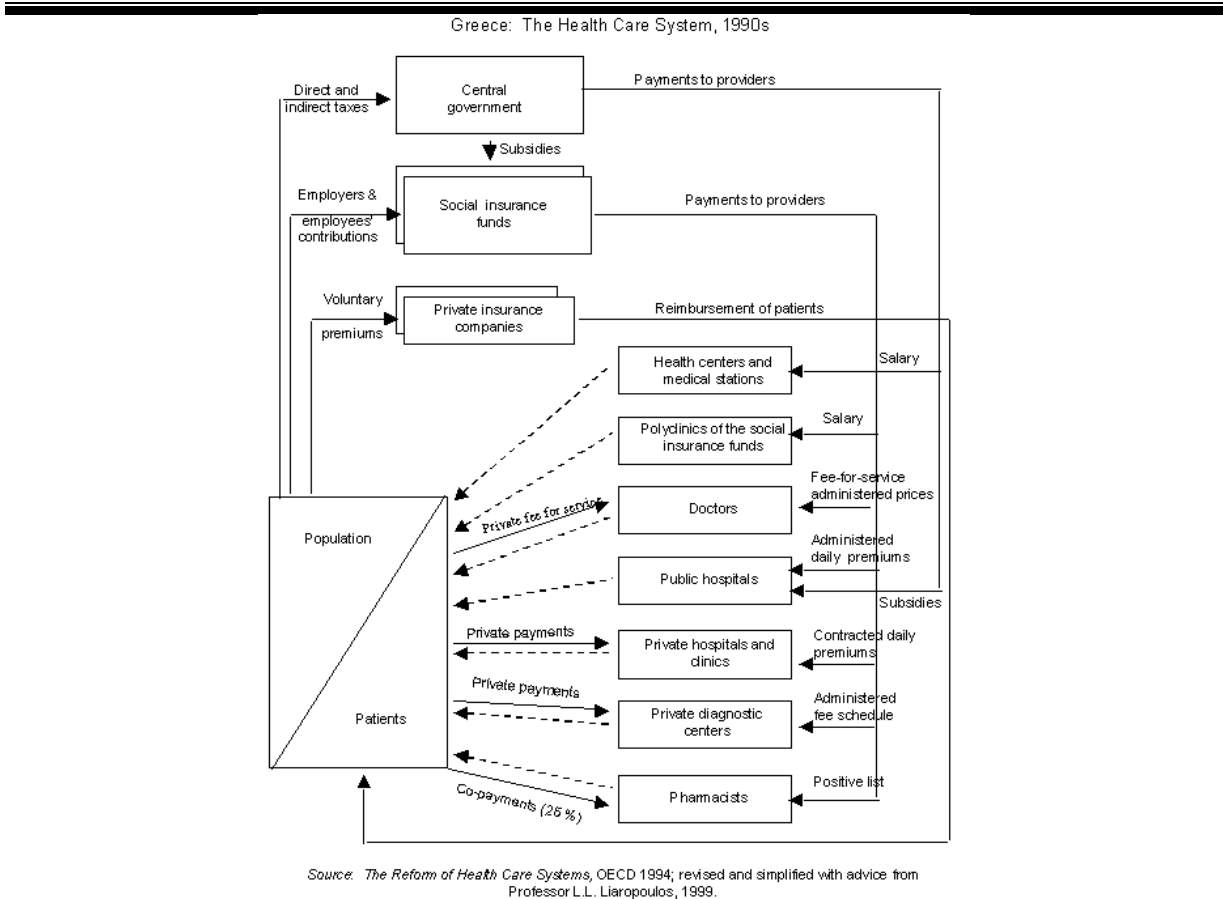
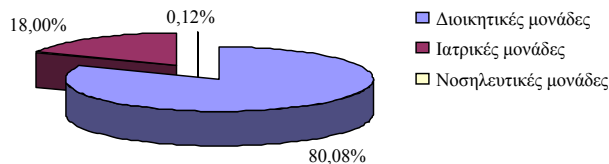


Figure 1: The Structure of the Healthcare system in Greece

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

The use of ICT technologies in the healthcare organisation of the public health sector in Greece is shown in Figure 2, as documented in 2001 as part of the effort to analyse the existing situation.



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**Figure 2:** Distribution of ICT in public healthcare organisation in Greece between administrative (blue), medical (purple) and nursing (white) units. (Taken from [6])

The available ICT technologies were primarily focused towards support of the administrative functions of the organisation (back office applications, such as finance, claims processing, procurement, etc). Very few applications exist with a focus to support the medical and nursing staff.

A recent (2007) status of the use of ICT by *general practitioners* in Greece has been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe' [7].

From the Greek country brief, we take over the following key findings:

"In terms of infrastructure, 79% of the Greek GP practices use a computer. 66% of practices dispose of an Internet connection. In Greece, broadband connections have not yet arrived in force; they are however already used in 44% of GP practices.

When it comes to the use of eHealth solutions, Greece shows results that are somewhat below the EU27 averages. Greece displays its best eHealth performance in the area of patient data storage. Yet even here usage rates lie below the EU27 average. Greece ranks fairly well with relation to the storage of medical patient data, which is used on average by more than two-thirds of GPs. In relation to the storage of radiological data, Greece even scores slightly above the EU27 average of 34%.

Computers are already used in consultation with the patients to some extent (20% of the GPs). This percentage however lags far behind the EU27 average of 66%. Decision Support Systems are still rather the exception than the rule. They are used by 12% of Greek GPs, which corresponds to one of the lowest usage rate with respect to this indicator in the EU27. Patient data transfer has as yet not very much arrived on the agenda of Greek GPs. The use of electronic networks for the transmission of medical patient data is not well established. Only 4% of the GP practices participating in the survey reported having exchanged medical data with other care providers via some sort of network, 3% having received analytic lab results this way. As concerns the transfer of administrative patient data, a very similar pattern appears: only 4% of the practitioners use networks to exchange administrative data with other health care professionals and 3% transfer administrative data to reimbursers this way".

### 3.3 National eHealth strategy

As part of the National Information Society programme for the period 2000-2006, significant investments were made and a large number of implementation initiatives were designed. They were ambitious efforts in implementing Regional Health Information Networks at each one of the Greek Regional Health Systems (R.H.S.). Their implementation has not been completed yet, but there is evidence that in a number of such initiatives the effort to introduce and use clinical and/or nursing applications will be successful.

The national eHealth Roadmap was launched in June 2006 by the Ministry of Health and Social Solidarity, as part of the National Strategy for Quality and Safety of Healthcare Services in the Information Society [15, 16]. It was based on a critical review of the national 2002 – 2006 ICT Action Plan and includes re-orientation where appropriate to accelerate

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national progress, incorporate new policies and align to the European eHealth Action Plan. An overview of this Roadmap can be found at [4], from which we present the main observations: The 2006 eHealth Roadmap sets out priorities and encompasses both strategy and action plans for the period 2006 – 2015 in the strategic areas of quality and safety of health services, which constitute the overriding strategic objectives. The revised eHealth Road map extends over the period 2006-2013, sets out priorities and encompasses both strategy and an action plan. The strategy is to establish the National Health Information System (NHIS) i.e. a national system for organising health related information. The implementation of an Electronic Patient Record system is the major objective and priority of the NHIS.

IASYS is the central IT infrastructure of the NHIS and provides the national interoperability framework intended to enable Greek health organisations seamlessly access and share health related information. The National Integrated Shared Care Record, together with the protocols agreed across the multitude of public and private health care organisations and services, are key elements of the IASYS strategy.

Implementation of the ten year eHealth Roadmap is split into the following three major phases:

1. Phase 1 (2006 – 2007) - Strengthening standardisation and communication infrastructures, and creating widespread market preparedness through strategic pilots (health cards, ePrescription, eCare), and legislative interventions;
2. Phase 2 (2007 – 2012) - Large-scale pilots, demonstrating and enabling Health Networks and integration at the regional level;
3. Phase 3 (2012 – 2015) - Integration at the national level.

### Implementation Priorities

The Ministry of Health and Social Solidarity, together with other direct beneficiaries will be implementing the 2006 – 2007 programme, which comprises:

- further development and/or deployment of the 17 regional Integrated Information Systems already in progress,
- standardisation activities,
- a Health Portal which serves both as the interface to the NHIS and as a platform for eHealth services to citizens,
- a study on the National Telemedicine Service, that will define support mechanisms (e.g. contracts and agreed protocols) for the coordinated delivery of telecare,
- across different health service delivery provision points,
- an eHealth Forum representative of all major stakeholders as a mechanism to address issues of national importance and for making shared informed decisions,
- an eHealth Forum Portal for professionals, which provides access to important professional tools and information (e.g. on health standardisation).

These priority areas will be implemented with associated and specific projects, such as:

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- smart card-based health insurance project for civil servants,
  - information system for the national ambulance service,
  - information system for organ-transplantation coordination and control,
  - information system covering transactions on patient charges between hospitals and insurance organisations,
  - EDI-based hospital procurement,
  - national blood-bank information system,
  - primary care information system,
  - medical libraries information system,
  - telemedicine.

### Future activities

The ten-year action plan is outlined in the strategic perspective section. It is intended to progress the following healthcare systems issues in each of the three implementation phases.

1. Information distribution infrastructures and systems, which will enable decentralised public health and welfare services to be based more effectively on evidence and operational data. These new systems will include emphasis on:
  - health prevention and promotion,
  - advanced tele-medicine applications,
  - a National ICT framework for biomedical technology management.
2. Health networking and telematics services, which are based on a secure data network linking health and social security bodies, and healthcare, community care and social-security professionals. These services include ePrescriptions; eReferrals; eLabs together with adequate provisions for appropriate accreditation, testing and certification. Such projects may be taken up in partnership with the private sector.
3. Development of information systems to improve the services provided by welfare and mental health bodies to the elderly and people with special needs.

Besides the eHealth Roadmap of the National Strategy for Quality and Safety of Healthcare Services in the Information Society and besides the public competitions for the implementation of the Regional Health Information Networks at each one of the Greek Regional Health Systems (R.H.S.), there are a few ongoing ‘pilot projects’ that aim at the development of electronic healthcare services.

Indicatively we mention the following two:

1. The project on the “**Designing and pilot application of an operating system of electronic prescription**”, that has been proclaimed by the Civil Servants’ Sickness Insurance Fund (OPAD). This project deals with the designing and the operation of an electronic prescription system that will offer an interoperable environment among OPAD



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(and the insured patient to it) and the entities of the primary healthcare (insured citizens, doctors, diagnostic centres, pharmacists). Given that it is a pilot project it does not aim at the direct and at national level operation of the system, but rather the definition of the architecture of the system, the recording of the procedures, the defining of the technologies and the spotting of eventual problems. Therefore the pilot project is planned to be realised in the city of Livadia and will include: 2.500 insured citizens, 24 pharmacies, 65 doctors, 3 of which bio-practitioners and 2 radiologists, 1 diagnostic centre and the General Prefectural Hospital. Main goals of the project are to electronically interconnect OPAD with its suppliers on the one hand, and the electronic support of the control and clearance procedures, which OPAD has to perform according to the current legal framework, on the other.

2. The project “**Development of an interoperable environment: (a) for Interconnection of the Social Insurance Funds and (b) for the electronic transactions between the Social Insurance Funds and Banks**”. The pilot project is considered as innovative and aims at the exploitation of technology for the establishment of an interoperable environment between the parties involved, through which they will be able to cooperate and exchange necessary information. Goal is the accumulation of experience and know-how throughout the project duration and its use in such a way, that they will assist in the integrated designing and implementation of the roll-out of the interoperable environment for all the Social Insurance Funds and the Entities that offer Primary Healthcare Services. A number of entities are involved in this project, such as the Social Insurance Funds: OGA, OAEE-TEBE, OAP-DEI, the Pharmaceutical Association of Attica, the Athens General Hospital “G.Genimatas”, diagnostic centres, such as EUROMEDICA, Iatropolis etc.

### 3.4 Regulatory framework for patients’ summaries

Greece doesn’t have legal provisions in the area of patients’ summaries. The second draft of the proposed law for the establishment and operation of the primary health care, includes a provision that the Electronic Health Card, which is initially seen only as a credit mechanism, shall, within five years from the adoption of the law, include all the necessary elements of the medical record of the insured patient, so that the family doctor and any other provider of primary healthcare can have access to them.

According to the national eHealth Strategy, the objective is to allow the unimpeded flow of health information within the healthcare system in an absolutely secure manner, following the citizen in his interactions and contacts with the system. In order to realize the vision of the National Electronic Health Record, a number of requirements must be met. These requirements include a National Identification System of citizens (patients), healthcare professionals and healthcare providers, interconnected with access and security policies, as well as rights for the execution of specific actions (e.g. referrals, prescriptions etc). In addition, the development of the national EHR is strongly dependent on the national standardisation of health on the level of services, systems, information, coding and terminology systems.

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**3.5 Regulatory framework for telemedicine**

There are no specific provisions in Greece with regard to telemedicine. The draft law for the establishment and operation of the primary health care includes telemedicine in the primary healthcare. More specifically it describes the provision of medical consultancy and services from a distance and via the use of advanced technologies and infrastructures, especially via a special telemedicine system and an open communication line. However this provision has already been heavily criticised by medical doctors because it is not defined whether the offering of the services will be done by all medical doctors of the system or there will be a specific entity for this purpose, equipped with the necessary technical facilities. Moreover there is no mention of the cost of telemedicine services.

**3.6 Regulatory framework for electronic prescriptions**

No specific legal framework exists for electronic prescriptions. A pilot project on electronic prescriptions has already been presented under 3.3.

**3.7 Overview of relevant legislation**

It is important to highlight that in **no** of the legal instruments of the Ministry of Health and Social Solidarity there is a reference to terms:

- electronic health,
- electronic procurement,
- personal data.

However, a look at the general legal document that have been adopted or proposed in the last five years shows an attempt for compliance with the European directives [8].

Some provisions regarding the establishment of eHealth in Greece are included in the draft law of March 2005 concerning the Quality and Safety of Healthcare Services and the National Health Information System and the draft law for the establishment and operation of the primary health care.<sup>2</sup>

Further relevant legislative texts relate to the practice of health care, in particular the practice of medicine Law 1565/1939 that regulates the practice of medicine. The new Code of Medical Ethics was ratified by Law 3418/2005 and regulated important issues with regard to the obligations of the doctors and their relations with patients.

Of particular interest to eHealth is law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data, as well as article 47 of law 2071/1992, which regulates rights of hospital patients.

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<sup>2</sup> The original titles of all policy and legal documents in Greek, as well as a link to their web location can be found in the end of this report.



## 4 Regulatory framework for the healthcare profession

### 4.1 Legal conditions for the practice of healthcare

For the medical profession in particular, the Council Directive 93/16/EEC, which was implemented in Greek law by P.D. 84/1986 and P.D. 38/2004, concerning the coordination of provisions in respect of activities of doctors, have influenced fundamentally education leading to general medical practice or medical specialization in Greece. Law 1565/1939 regulates the practice of medicine (and applies also to dentists). In order to practice medicine and use the title of medical doctor, an official permit is needed, which is provided by the Minister of Health. In order to obtain this permit the applicant shall:

- a) have legally acquired a diploma of a Medical School of a Greek University. Holders of diploma of a Medical School acquired abroad, they shall succeed in the procedure foreseen by law (for EU citizens, see also below),
- b) be Greek citizen, who has not been deprived of his political rights and is not rendered legally incompetent,
- c) have served his military obligations, if any, or have been exempted from these,
- d) not be convicted for theft, fraud, defalcation, extortion, forgery, and not be convicted repetitively for delinquency that entails the deprivation of his political rights
- e) mention in his application the Medical Association in the district of which he plans to have his professional establishment

Exceptions are foreseen for Greek expatriates who don't have the Greek citizenship and for foreign medical doctors. P.D. 84/1986, as updated by P.D. 38/2004, defined the conditions under which citizens of the European Member States can be established and exercise medicine in Greece, after they obtain a permit for it. The details for the permit are described in the same law.

The exercise of medical practice is not allowed before the inscription to the local Medical Association. Doctors that also have the degree of pharmacist or dentist are not allowed to maintain pharmacies, dentistry, or other similar establishments, unless they give up the exercise of medicine and the use of the title of medical doctor (Art.6§3 of the Code of Medical Ethics).

Details about the legal conditions of all healthcare professions can be found here:

<http://www.mohaw.gr/gr/theministry/minservices/epaggelmataygeias>

### 4.2 Control over the practice of medicine

The practice of medicine in Greece is supervised by the Medical Associations (in the majority of cases it will be the local Medical Association, which the doctor belong to). As already mentioned citizens of the European Member States can be established and exercise medicine in Greece, after they obtain a permit for it. No permit is needed for foreign doctors that exercise lawfully the medical profession abroad, if they come to visit a patient.

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The Medical Associations are supervising the observance of the rights and obligations of the doctors. The Medical Associations are also ensuring the observance of the rules included in the Code of Medical Ethics that contains rules regarding the obligations of the doctor towards the patient, medical secrecy etc. It shall be pointed out that the Code of Medical Ethics is ratified by law 3418/2005.

All medical associations as well as the Pan-Hellenic Medical Association are under the supervision of the Minister of Health, who has the right to impose sanctions, when provided for by law.

**4.3 Professional liability**

As already analysed under 4.2, the doctor has disciplinary liability towards the Medical Associations. However both the civil liability and the criminal liability of the doctor for damage or injury caused by improper performance of the duties entailed in the discharge of his professional functions, are governed by the general rules of civil and criminal law respectively.

When the doctor causes damages to the patient during the exercise of his activities, then there is civil liability of the doctor towards the patient and there is an obligation for compensation. As the general rules apply in these cases as well, the burden of proof lies with the plaintiff, i.e. with the patient. There are opinions however who call for a reversal of the burden of proof in cases of medical liability. The Greek courts have recognised the relation between doctor and patient as a contractual relation and it can also be interpreted as offering of medical services or the execution of medical contract.

Penal liability exists when the doctor infringes legal goods of the patient, such as physical injury or death. The majority of penal cases with regard to the criminal liability of the doctors are offences that were not internationally committed.

**4.4 Professional secrecy<sup>3</sup>**

In general, the medical secrecy is safeguarded in a series of legal provisions, like Art 371 of the Penal Code, Art. 22 and 23 of Law 1565/1939 regarding the exercise of the medical profession, the Code of Medical Ethics (Law 3418/2005) and Article 47 of Law 2071/1992, which safeguards the patient's right for the secrecy of the information that relates to him. Physicians are obliged to protect the confidence entrusted by their patients. According to article 13§1 of the Code of Medical Ethics the physician has the obligation to keep medical information confidential. This obligation is absolute. Paragraph 2 of the same article stipulates that "in order to strictly and effectively respect medical secrecy, the physician has to observe the necessary discretion regarding his collaborators, assistants or third parties which take part in one or another way or support the medical service". He shall also take every necessary measure to safeguard confidentiality even after the termination of his medical practice. The duty to respect medical secrecy may be waived by the consent of the person concerned,

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<sup>3</sup> Based on [9]

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except when this consent is not valid as in case of error, deceit, deception, physical or psychological violence or when it violates human dignity (14§3 Code of Medical Ethics).

In particular, according to article 8 of the Code of Medical Ethics, the physician is obliged to take every possible measure to ensure that information that could lead to a breach of medical confidentiality is excluded from professional or scientific books or articles. Special care shall be taken so that the identity of a patient is not disclosed therein. The breach of that obligation may give rise to a claim for damages to the party aggrieved by such a breach of duty.

According to article 20 of the Code of Medical Ethics the strict maintenance of medical secrecy is obligatory for all physicians serving in social insurance organizations or funds under public or private law, of any kind or category. Any declaration contrary to the principle of medical secrecy is to be avoided. The only physicians exempt from this obligation are those executing a task of inspection, certification or evaluation, and then only within the limits of their instructions and the specific task undertaken. Under no circumstances may a doctor undertake an assessment of a patient on behalf of a third party when that patient is or has been under his care.

Article 371 of the Penal Code imposes upon the physician a legal obligation not to disclose confidential information on patients which he has learned in the course of their medical practice, not only from patients themselves but from other sources as well (professional confidentiality duty). The same obligation rests with nurses and paramedical personnel who are also bound to their professional duty of secrecy on medical information circulating within the team. This is commonly known as “shared medical secret” [10].

## 5 Processing of personal health data

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

The 1981 Council of Europe Convention regarding the protection of individuals from the automated processing of personal data was ratified by Greece over a decade after it was signed, with Law 2068/1992 for the ratification of the Council of Europe Convention for the Protection of Individuals with regard to automatic processing of personal data. Despite the obvious need for a data protection framework in Greece, successive attempts to introduce a dedicated data protection law in 1985, 1989, 1990, 1991 and 1992 all foundered. Finally, Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data was introduced, incorporating Directive 95/46/EC into Greek law, and establishing the Greek Data Protection Authority. The law has been modified by laws 2623/1998, 2703/1999, 2721/1999, 2819/2000, 2915/2001, 3068/2002, 3090/2002, 3156/2003, 3471/2006 and 3625/2007.

Besides the Data Protection Law, Article 9A was added to the Greek Constitution during the Constitutional Revision of 2001 and provides for the protection of personal data and the establishment of the relevant independent authority, i.e. the Greek Data Protection Authority. The new Article reads as follows: "All persons have the right to be protected from the collection, processing and use, especially by electronic means, of their personal data, as specified by law. The protection of personal data is ensured by an independent authority, which is established and operates as specified by law".

Generally speaking the Greek data protection law is quite similar to the European directive. Therefore there is almost literal parallelism between the Greek law and the Directive with regard to:

- the definitions of 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) but, in accordance with the Directive, the Greek legislator has enacted detailed rules on the further processing of personal data for scientific, historical or statistical purposes (art. 4(1)(d) Greek law);
- 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 and 14 of the Directive), after the exercise of which the data controller has to reply within an exclusive period of 15 days;
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive), with exceptions related to health data;

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- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Greek Data Protection Authority can be read at [www.dpa.gr](http://www.dpa.gr)).
- liability for damages as a result of unlawful processing (art. 23 of the Directive);
- transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

It is important to mention that the Greek data protection law contains specific provisions regarding the interconnection of files in its Article 8.

### 5.2 Transposition of article 8 of Directive 95/46/EC (with focus on health data)

The Greek data protection law contains a definition of the term “sensitive data” in Article 2(b). The definition of sensitive data was modified by law 3471/2006 and 3625/2007 and today reads as follows:

“Sensitive data” shall mean the data referring to racial or ethnic origin, political opinions, religious or philosophical beliefs, participation in a trade-union, health, social welfare and sexual life, and the related to criminal charges or convictions, as well as the participation to associations related to the aforementioned.

Especially for the related to criminal charges or criminal convictions is it possible to allow their publication only by the public prosecutor’s office for the crimes that are mentioned in Article 3 paragraph 2 subparagraph b’ by order of the responsible public prosecutor of the regional court or the court of appeal, if the case has come to the Court of Appeals. This publication aims at the protection of the public, the minors, the vulnerable or weak population teams and at the easier realisation of the claim of the State for the punishment of the aforementioned crimes”.

Article 7 of the Greek data protection law regulates the processing of sensitive data and is formulated as follows:

“1. The collection and processing of sensitive data is prohibited.

2. Exceptionally, the collection and processing of sensitive data, as well as the establishment and operation of the relevant file, will be permitted by the Authority, when one or more of the following conditions occur:

a) The data subject has given his written consent, unless such a consent has been extracted in a manner contrary to the law or *bonos mores* or if law provides that any consent given may not lift the relevant prohibition.

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- b) Processing is necessary to protect the vital interests of the data subject or the interests of a third party as foreseen by law, if he is physically or legally incapable of giving his consent.
  - c) Processing relates to data made public by the data subject or is necessary for the recognition, exercise or defence of rights in a court of justice or before a disciplinary body.
  - d) Processing relates to health matters and is carried out by a health professional subject to the obligation of professional secrecy or to relevant codes of conduct, provided that such processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services.
  - e) Processing is carried out by a Public Authority and is necessary for the purposes of aa) national security, or bb) criminal or correctional policy and pertains to the detection of offences, criminal convictions or security measures, or cc) protection of the public health, or dd) for the exercise of public tax control or public control on social welfare services.
  - f) Processing is carried out exclusively for research and scientific purposes provided that anonymity is maintained and all necessary measures for the protection of the persons involved are taken.
  - g) Processing concerns data pertaining to public figures, provided that such data are in connection with the holding of public office or the management of third parties' interests, and is carried out solely for journalistic purposes. The Authority may grant a permit only if such processing is absolutely necessary in order to ensure the right to information on matters of public interest, as well as within the framework of literary expression and provided that the right to protection of private and family life is not violated in any way whatsoever.
3. The Authority shall grant a permit for the collection and processing of sensitive data, as well as a permit for the establishment and operation of the relevant file, upon request of the Controller. Should the Authority ascertain that processing of sensitive data is carried out, the notification of the existence of such a file pursuant to article 6 of this law is considered to be a request for a permit. The Authority may impose terms and conditions for a more effective protection of the data subjects' or third parties' right to privacy. Before granting the permit, the Authority shall summon the Controller or his representative and the Processor to a hearing.
4. The permit will be issued for a specific period of time, depending on the purpose of the data processing. It may be renewed upon request of the Controller.
5. The permit shall necessarily contain the following:

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- a) The full name or trade name or distinctive title, as well as the address, of the Controller and his representative, if any.
  - b) The address of the place where the file is established.
  - c) The categories of personal data which are allowed to be included in the file.
  - d) The time period for which the permit is granted.
  - e) The terms and conditions, if any, imposed by the Authority for the establishment and operation of the file.
  - f) The obligation to disclose the recipient or recipients as soon as they are identified.
6. A copy of the permit shall be registered with the Permits Register kept by the Authority.
7. Any change in the data referred to in paragraph 5 shall be communicated without undue delay to the Authority. Any change other than a change of address of the Controller or his representative shall entail the issuance of a new permit, provided that the terms and conditions stipulated by law are fulfilled”.

The Greek data protection law foresees in Article 7a exemptions from the obligation to notify and receive a permit from the Data Protection Authority. The relevant provisions with regard to health data are the following:

“1. The Controller is exempted from the obligation of notification, according to article 6, and the obligation to receive a permit, according to article 7 of the present Law in the following cases:

[...]

b) When processing relates to clients’ or suppliers’ personal data, provided that such data are neither transferred nor disclosed to third parties. In order that this provision may be applied, courts of justice and public authorities are not considered to be third parties, provided that such a transfer or disclosure is imposed by law or a judicial decision. Insurance companies, for all types of insurance, pharmaceutical companies, companies whose main activities involve trading of data, credit and financial institutions, such as banks and institutions issuing credit cards are not exempted from the obligation of notification.

[...]

d) When processing relates to health data and is carried out by doctors or other persons rendering medical services, provided that the Controller is bound by medical confidentiality or other obligation of professional secrecy, provided for in Law or code of practice, and data are neither transferred nor disclosed to third parties. In order that this provision may be applied, courts of justice and public authorities are not considered to be third parties, provided



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that such a transfer or disclosure is imposed by law or judicial decision. Legal entities or organisations rendering health care services, such as clinics, hospitals, recovery and detoxification centres, insurance funds and insurance companies, as well as Controllers processing personal data within the framework of programmes of telemedicine or provision of health care services via Internet, don't fall under the exemption.

[...]

2. In every case of paragraph 1 of the present article, the Controller is subject to all obligations specified by the present law and is obliged to conform with any special processing rules issued by the Authority pursuant to article 5 paragraph 3 of the present law.

3. [...]"

The following comments can be made with regard to the provisions of the Greek data protection law with regard to health data:

- Personal data referring to health is not further defined. Greek doctrine and the Greek DPA<sup>4</sup> generally refers to the definition of the Council of Europe recommendations regarding the processing of health data: "The meaning of the term "personal data concerning health" (...) includes information concerning the past, present and future, physical or mental health of an individual. The information may refer to a person who is sick, healthy or deceased. This category of data also covers those relating to abuse of alcohol or the taking of drugs.", as well as the definition included in Opinion 13/1999 on the Ethical issues of healthcare in the information society of the European Group on Ethics in Science and New Technologies which states that "Personal health data' encompass a wide range of information about an individual, which all touch upon an individual's private life. A health biography could include, not only basic medical data: a history of all medical diagnoses, diseases and medical interventions, medications prescribed, test results, including imaging, etc..."
- The term "health" in the Greek DPL includes any information that relates to the biological existence and the mental health of a person. Therefore, according to this definition, sensitive data is any data which reveals information about the physical and mental condition of a person, his deficiencies and disabilities, dietary or other relevant needs and the medical record of a patient. The term "health data" includes all medical data<sup>5</sup> of a person in the broad meaning of the term, including information on prescriptions, drug taking and use of narcotics, (but not their supply when it is not done for the person's own use) and also the wider category of genetic data, primarily

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<sup>4</sup> Personal Communication with the Greek DPA

<sup>5</sup> Indicatively see Ruling 15/2006 of PDPA.



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hereditary characteristics and genetic code<sup>6</sup>. Ambiguity prevails over the classification of “biometric data”, i.e., bodily characteristics such as skin, eye iris, fingerprint, face characteristics, and “behavioural characteristics” such as voice, lip movement, signature, *etc.* The Greek DPA seems to consider these as “simple data” (Decision 245/2000); however, if such biometric data lead to revealing racial characteristics (e.g., skin colour) or the genetic code, then they are classified as “sensitive data”. Lastly, a special category of medical data has been established by Law 2737/1999 on “human organ transplants.” In Article 9, this law classifies as sensitive data the contents of the National Records for donors and the recipients<sup>7</sup>. The Greek DPA published in 2001 an opinion on the “analysis of genetic data for the purposes of investigation and prosecution of crimes” (Opinion 15/2001), where it is mentioned: “In any case, genetic data relate with health, but can at the same time be considered as data that refer to racial or ethnic origin”.

- Processing personal data concerning health on the basis of the consent of the data subject is only possible if the controller has obtained a written consent (Art. 7§2(a) Greek DPL).
- Any person who processes data related to health matters shall be carried out by a health professional subject to the obligation of professional secrecy or to relevant codes of conduct, provided that such processing is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services. The term “health professional” is not defined but according to the majority opinion in legal doctrine and the interpretation of the Greek DPA, the term not only refers to physicians but rather to a broad spectrum of healthcare professions. The Greek DPA recognised in Decision 51/2002 that the health data contained in a prescription can be legally processed by the doctor who wrote the prescription and the pharmacist, who executes it, as they are both bound by professional secrecy, the breach of which incurs penal sanctions as well. However, the communication of these sensitive data from the pharmacist to the any third party (such as pharmaceutical companies, drug traders etc.) in order to obtain the medicine that is mentioned on the prescription is rendered an unlawful processing. Concluding the Greek DPA recommended the pharmacists to take every necessary measure to ensure the secrecy of the medical prescriptions and avoid their communication to third parties.
- The Controller is **exempted from the obligation to receive a permit when processing relates to health data** and is carried out **by doctors or other persons rendering medical services, provided that the Controller is bound by medical confidentiality or other obligation of professional secrecy, provided for in Law or code of practice**, and data are neither transferred nor disclosed to third parties. It is important to point out that the Greek law still expects the legal entities or organisations rendering health care

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<sup>6</sup> Article 5.5 of the Constitution expressly protects the “genetic code.” The PDPA in its Ruling 115/2001 has held that it is absolutely prohibited to process such data within the context of employment (“supersensitive data”). Also, in its Ruling 15/2001, the PDPA had set a series of strict conditions for the use of genetic data (DNA) for criminal investigations. However, recent amendment by Law 3625/2007 has excluded from the DP Law’s scope of application personal and sensitive data, gathered by judicial authorities for the purpose of verification of crimes.

<sup>7</sup> Analysis made by [11]

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services, such as clinics, hospitals, recovery and detoxification centres, insurance funds and insurance companies to receive a permit when processing health data. The same counts for processing of personal data **within the framework of programmes of telemedicine or provision of health care services via Internet** (Art. 7A§1(d) Greek DPL). The Pan-Hellenic Association of Physical Therapists asked to be exempted from the notification obligation and the one to receive a permit from the Data Protection Authority. The Greek DPA adopted Decision 60/2005, which held that physiotherapists are not exempted from the notification/permit requirement, because their code of ethics did not provide in a legally-binding way for a professional secrecy duty. The Greek DPA decided to allow the exemption of the physical therapists from the obligations to notify and receive a permit, only when there will be a modification of the Memorandum of the Association, which will explicitly foresee the disciplinary sanction of temporary or permanent expulsion from the Association for everyone that breaches the professional secrecy duty, with simultaneous notification of the expulsion to the responsible body for the supplying of the official permit for the exercise of the profession of the physical therapist at national level.

- **Insurance companies**, for all types of insurance (i.e. also health insurance companies), **pharmaceutical companies** [...] are not exempted from the obligation of notification (Art.7A§1(b) Greek DPL).
- The Greek legislator made use of the exception of Article 8§4 of the Data Protection Directive that allows Member States, for reasons of substantial public interest, to lay down additional exemptions to the rule of general prohibition of processing of sensitive data. Article 7§2(e) foresees, among others, such an exemption for the protection of public health. The Greek Data Protection Authority clarified in its opinion 61/2007 that since this provision is exceptional, it shall be interpreted narrowly. The Greek DPA rejected the request of two public hospitals to transmit sensitive data to the Ministry of Health and Social Solidarity in order to infer conclusions on the degree of patients' satisfaction by the offered medical services at public hospitals. The Greek DPA mentioned however that the issue would be different if the survey was conducted by the public hospitals themselves and not by the Ministry, as in this case there would be no issue of transfer of data to third parties.

### 5.3 Information and access rights of data subjects

With regard to the exercise of the right of access, Article 12§6 stipulates that “Data pertaining to health matters will be communicated to the data subject by a medical doctor”. As for the rest, the general provisions of Article 11 Greek DPL on the right to information and Article 12 on the right of access apply.

### 5.4 Organisational and technical measures

According to Article 10§3 of the Greek data protection law “[t]he Controller must implement appropriate organisational and technical measures to secure data and protect them against

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accidental or unlawful destruction, accidental loss, alteration, unauthorized disclosure or access as well as any other form of unlawful processing. Such measures must ensure a level of security appropriate to the risks presented by processing and the nature of the data subject to processing.[...]”. The Greek Data Protection Authority ruled in its Decision 15/2006 that Art. 10 of the law applies also to the secure destruction of personal data after the end of the period necessary for the realisation of the purpose of the processing, so that they will not become object of unlawful processing, like dissemination to third parties. Based on this reasoning the Greek DPA fined a private clinic for not disposing carefully of paper information that contained personal and sensitive information. The DPA referred also to its Opinion 1/2005 on the secure destruction of personal data after the end of the period necessary for the realisation of the purpose of the processing.

**5.5 Other relevant rules regarding personal data protection in the context of health related data**

Article 8 of law 3144/2003 regulates issues regarding the protection of personal data of employees and reads as follows:

“1. The recording and processing in the personal booklet of professional danger of the employee of elements or data other than the results of medical and laboratory tests, he is subject to each time, according to the provisions of Art. 4§14 of the Presidential Decree 17/1966.

Furthermore medical data are allowed to be collected, under attention of the employee, in order to become subject of processing, only if this is absolutely necessary for: a) the evaluation of his suitability for a specific position or labour, b) for the fulfilment of obligations of the employer for the hygiene and the safety of the labour and c) for the foundation of rights of the employee and the respective attribution of social benefits.

2. Everyone who records or collects or processes elements or data in breach of paragraph 1 is punished with administrative and penal sanctions that are foreseen in the provisions of Articles 21 and 22 of law 2472/1997 [i.e. the Greek data protection law] respectively. In case of economic loss or non-material damage, Article 23 of law 2472/1997 applies.

3. A common decision of the Ministers of Labour and Social Insurance, and of Health and Welfare regulates the specific issues regarding the maintenance and the content of the personal booklet of professional danger, the collection and processing of additional data with the consent and diligence of the employee, the imposition of the sanctions of paragraph 2 of this article and any other detail necessary for the enforcement of this article”.

## 6 Rights and duties of healthcare providers and patients

In Greece the relation between patients and physicians is regulated by provisions in various legal acts and not by specific legislation. The development of legislation relating to patient rights in Greece has in the last fifteen years undergone four major phases. In the period up to 1992, patient rights in Greece were indirectly addressed through relevant provisions in Civil, Penal, Administrative and Disciplinary Law. In 1992, based on the European Charter of Hospital Patients' Rights of 1979, broader health care reform legislation contained provisions directly addressing the rights of hospital patients (Article 47 of Law 2071/1992). In 1997 further provisions extended the rights of patients granted in 1992 to the entire population, and in addition provided for the implementation of the legislative provisions. In 2005 the most important change in medical law in Greece in the last years took place. The new Code of Medical Ethics was ratified in that year by Law 3418/2005. The Code regulates important issues on the relation between doctor and patient. The description of the new Code of Medical Ethics, along with reference to different legal documents that define the rights and duties of healthcare providers and patients, in the following chapter has been adapted from the booklet on "Patient Rights in the EU – Greece"[9].

Special legal provisions exist with regard to transplantations (Law 2737/1999), assisted reproduction (law 3089/2002, 3305/2005), mentally ill and hospital patients (law 2071/1992).

### 6.1 Right to informed consent

The right to informed consent is protected by the Greek Constitution and other Greek legislation under which the Penal Code, Article 47 of the Law 2071/1992 and Article 12 of the Code of Medical Ethics. Article 47 (3) of Law 2071/1992 (on the rights of the hospital patient) stipulates that "every patient shall have the right to give or refuse his consent to any diagnostic or therapeutic procedure intended to be carried out on him", while Article 12 of the Code of Medical Ethics also deals with the consent of the informed patient, when stipulating "the physician shall not proceed with the execution of any medical act, unless consent has been secured". The same Article specifies the information to be given to the patient prior to the consent. Consent can be so called *presumed* in case of trivial diagnostic or therapeutic procedure without any risks or so commonly practiced. Whether presumed consent of the patient exists in a case, will depend on the nature of the medical intervention, its possible consequences and the attitude of the patient. [10]

There are certain exceptions which permit medical intervention to take place without the patient's consent (so-called "non-consensual medical actions"). According to Greek law, these non-consensual medical actions are defined to be "all those interventions on the part of the doctor on the patient (preventive, diagnostic, curative) for which the decision on whether or not the intervention should be undertaken is exclusively the doctor's responsibility". In the case of suicide attempts or hunger strikes, but only in the event that the patient's life is in danger, the doctor is obligated to intervene against or in spite of the patient's wishes. This obligation also exists in urgent cases which require surgery and in case of so called extended operations [12].

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Written consent is not obligatory. According to research on patient rights in Greek hospitals, only 5,5% of all patients are required to provide their consent in writing, depending on the hospital. Written forms of contracts are signed more and more by the patient and sometimes by the physician in cases lacking any medical indication, such as sterilizations or cosmetic operations, though they are not considered as a substitute for informed consent of the patient, especially when the “technical” language of the contract is not fully understood by the patient.

Article 12 (2) of Act 3418/2005 on the Code of Medical Ethics provides with regard to minor patients: “In case of a minor patient, consent has to be given by the person bearing parental responsibility or the legal custodian. The opinion of the minor is taken into consideration if the physician is of the opinion that bearing in mind the minor’s age and mental and emotional maturity he is able to understand his health condition as well as the nature, the consequences, the results and the risks of the treatment”. According to the Order of Physicians in Greece a distinction has to be made between two categories of minors: those who have attained the age of sound mind, and the others. It is not expressed in terms of an age limit. The physician should decide considering the personality of the child, the medical treatment proposed, the family and social background etc. Generally, the age of 15 to 16 years is considered as the turning point between legal incapacity and medical capacity. A mature minor may give his consent alone, but the consent of his parents may also be required. The physician has always to evaluate the situation and to judge whether the consent of the parents will also be required. If the parents of a minor refuse to consent and the life of the minor is in danger, the Greek common medical practice on youth protection allows an *ultimum remedium*. The duty to rescue the minor obliges the physician to act on his own initiative.

**6.2 Rights related to information about the state of health**

According to article 47 (4) of the Hospital Act every patient has the right to request information regarding his situation. Moreover Article 11§1 of the Code of Medical Ethics stipulates that “a physician bears a duty of candor towards the patient. He shall inform his patient, fully and comprehensibly, on the true status of his health, the content and results of the medical act proposed, the consequences and the possible risks from its performance, the side effects, the alternatives and the possible time of cure, so that the patient may shape a complete picture of the medical, social, economic factors and consequences of his condition and proceed with his decision.” Article 11§3 stipulates further that “special attention has to be paid when informing a patient in case of special treatment such as transplantations, change of sex, in vitro fertilization, esthetic and plastic surgery.” Article 11 (2) of the Code of Medical Ethics stipulates for the patient a right not to know and for the physician an obligation to respect this right. In these cases, the patient is entitled to ask the doctor to inform exclusively other persons, suggested by him.

There is no obligation to inform the patient in writing, thus the right to information in Greece is solely on an oral basis. [13]

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

According to article 14§1 of the Code of Medical Ethics, “the physician must keep up a medical file electronically or in printed form that contains data that are (unbreakable) related to the illness or health of his patients”. Article 14§3 of the Code obliges the hospitals to keep in their archives all the results of patient's tests. Private Doctor's offices shall keep their archives for at least ten years after the last visit of their patients and public health care facilities for twenty years (§4).

According to article 14§2 of the Code of Medical Ethics a medical file must contain the patient's name, sex, age, profession and address, the dates of consultation, every essential element of the health care to the patient such as his illnesses and the reason for the consultation, the diagnosis and the action taken. Article 14§7 stipulates that a medical file may not contain any judgments or comments about a patient except when they concern his illness. No notes on any other matter than a patient's disease shall be recorded in his file.

Article 14§8 of the Code of Medical Ethics stipulates that the patient has the right to access his medical file and to receive a copy of his file. Article 16 of Law 1599/1986 on Citizen – State relations provides that a subject may not access written documents covered by medical confidentiality that refer to third persons. These documents are accessible only by persons to whom the information therein refers, and only within the presence and under the assistance of a physician. The exact role of this physician remains unclear. It may be that he will make known only a selection of the data so as not to cause distress or damage to health of the patient. It is also possible to provide such information to legal or physical persons having a right or legal interest by following a procedure established by article 1460 of the Civil Code and article 12 of the Code of Medical Ethics.

As already stipulated, article 14§8 of the Code of Medical Ethics also recognizes to the patient a right of access and a right to receive a copy of the medical file. There is no right to copy the medical file for third parties. If the patient has died, the patient's close relatives may exercise the right to access the medical file. A third party has no right to access the patient's file (Article 14§9 code of Medical Ethics). Only judicial or prosecutorial authorities may ask for access during the execution of their duty or other organs of the Greek State having this right under their constitutions.

**6.4 Right to free choice**

The Draft Law for the establishment and operation of the primary care provides in its Article 5 that the patient was the right to freely choose his family doctor.

**6.5 Right to the protection of informational privacy**

The right of the patient to informational privacy and the obligation of physicians to respect this aspect of the patient's privacy are safeguarded in Greek law. The most important pieces of legislation are the Code on Medical Ethics, Law 1599/1986 on the State – Citizen relationship, law 1805/1988 on the updating of the criminal record, the modification of penal



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provisions and the adjustment of other related matters and Law 2400/1996 which ratified Protocol 11 of the Convention on Human Rights and Fundamental Freedoms. Law 2071/1992 in its Article 47 on the rights of the hospital patient also contains a disposition to protect the privacy of the patient: “every patient shall have the right, to the extent that it is genuinely possible, to the protection of his private life” (article 47§6). This includes the right to expect appropriate and confidential treatment of data, documents and files containing personal information, including observations and medical findings.

**6.6 Right to medical secrecy/ confidentiality**

The right to medical secrecy corresponds to the obligation of the healthcare professionals that has already been presented under 4.4.

## **7 Identity management in the health sector**

No identity management system for the Greek healthcare sector including the identities of patients, healthcare professionals and other stakeholders is currently available. The Draft law for the establishment and operation of the primary health care introduces the Electronic Health Card, which is however seen as a credit mechanism. Aim of this provision is the control of the patient's use of the primary healthcare. The Electronic Health Card shall, within five years from the adoption of the law, include all the necessary elements of the medical record of the insured patient, so that the family doctor and any other provider of primary healthcare can have access to them.

According to the national eHealth strategy, the national health card should support identification services for accessing personal information and for obtaining healthcare services. Efforts will be made on a national level so that the card will be interoperable and gradually common for both Health and Social Welfare services, so that it can ensure the automatic payment of health care expenses. The necessary mechanism will be created so that the national health card will be standardised with the participation of all relevant actors and organisations. In parallel, the Ministry of Health will establish a mechanism for assurance and accreditation of issued cards. In that way, it will be possible to enable parallel issuing of cards by several bodies, provided that the national standard has been followed and the card has been certified before its distribution.

### **7.1 Overview**

Identification in Greece services is traditionally relied on the mandatory paper based identity card in conjunction with the information contained in population registers held by municipalities. There are currently no concrete plans for an eID card. It is notable that in Greece there exists no central national register like in other EU Member States, but municipalities and communes keep (electronic) registers of inhabitants, which contain information on the personal and family status. Information regarding legal entities was traditionally kept in paper based trade registers, which were maintained in Court Registers and the Departments of the Ministry of Commerce, whereas in case of public limited and limited liability companies the relevant acts were also published in the Government Gazette. Law 3419/2005 provided for an electronic General Register for legal persons, including most companies' forms, and for natural persons, which are merchants. However, this electronic Register did not start its functioning yet.[RD9]

### **7.2 Patient identification**

In the healthcare sector the identification of the patient is done via a health booklet, which is issued by the insurance company of the patient. Since there is still no uniform insurance system in Greece, each insurance company issues different health booklets for their patients. The draft law of March 2005 (still draft) concerning the Quality and Safety of Healthcare Services and the National Health Information System, foresees also a Health-ID number. The necessary policy framework for information access management is still missing. There is also



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the need to establish the infrastructure for professional identification, which should take into account differentiation on the basis of specialization differences, as well as practical experience differences. Currently, there is a unique patient number per hospital, and a single patient number is used on a regional level (DYPE). This regional number however is not always functional on all hospital systems, but rather vendor-dependent [1].

**7.3 Authentication of healthcare professionals**

A registry of the medical doctors is kept at the local Medical Associations they belong to. A copy of each registry is sent to the Pan-Hellenic Medical Association and the Health Centre (the regional Health Centre the medical Association belongs to). Every change in the local registry shall also be communicated both to the Pan-Hellenic Medical Association and the Health Centre.

**7.4 Exchange of health-related data**

No electronic exchange of health-related data is currently foreseen by law. According to the national eHealth Strategy, the objective is to enable the unimpeded flow of health information within the healthcare system in an absolutely secure manner, following the citizen in his interactions and contacts with the system. In order to realize the vision of the National Electronic Health Record, a number of requirements must be met. These requirements include a National Identification System of citizens (patients), healthcare professionals and healthcare providers, interconnected with access and security policies, as well as rights for the execution of specific actions (e.g. referrals, prescriptions etc). In addition, the development of the national EHR is strongly dependent on the national standardisation of health on the level of services, systems, information, coding and terminology systems.

## **8 Electronic prescription**

The Greek legislation does not currently contain any provisions regarding electronic prescription.

The prescription is a private official document for which Article 8 (b) P.D. 312/1992 mentions that “every prescription shall carry in print the name and last name of the doctor, his specialisation, his address and phone number, as well as the date of issuing, his signature and stamp”.

The Circular of the Ministry of Health and Welfare on “Guidelines for the prescription of pharmaceutical products” determines the basic elements of a prescription. As specified in its Article 3, the prescription shall be clearly written and shall (necessarily) contain the date, the name and last name of the patient, the full and clear diagnosis and/or the justification for the prescription (e.g. preventive, antimicrobial treatment), up to three pharmaceutical products (name, type, quantity, number of boxes and dosing shape), dosing instructions, signature and name/last name or stamp of the doctor.

Besides this general provision, prescriptions are regulated by a complex web of regulatory texts which have been enacted in the framework of the health insurance. For instance, Art. 2 P.D. 88/1998 foresees a unified prescription form to be used by the State (for civil servants) and the insurance entities that are under the Ministry of Labour and Social Insurance and regulates all the details regarding this.

According to an opinion highly supported by doctors, pharmacists and legal scholars, the full name of the diagnosis can and should be substituted by the code ICD-10 of the disease, which is only comprehensive by doctors and in this way the secrecy of the medical history of the patient is protected.

For medication that contains addictive substances, there are specific rules deriving from Laws 1729/1987 and 2161/1993, and a specific prescription on drugs shall be issued. The doctor shall have a special duplicate booklet of prescriptions, each of which shall have at least 2 numbered pages validated by the Ministry of Health. This type of medication is commonly known as “controlled drugs”.

The draft law for the establishment and operation of the primary health care foresees in Article 5 that the prescription of medicine will be allowed to every entity, public and private, that is placed among the General System of Primary Health Care. However this provision has become a highly debated issue as it broadens the existing right of prescription which is only allowed by doctors and dentists and this is how the Pan-Hellenic Medical Association would like it to remain [14].

The Information Society has funded a €1 million pilot that tested the establishment of a connection between 2 hospitals and the association of pharmacists for the purposes of prescription reimbursement. The ELTA-DIAS networks were used for this purpose.

Under measure 2.4 of the Strategic eHealth Plan, funds for implementing IT in the regions also in the area of health are made available. The possibility of connecting Regional Data Centres, hospitals and primary care centres for access to an individual's prescription profile is being investigated, but not the option of pharmacy dispensing. At present, Primary Care Centres get their medications from hospitals and dispensing to patients also takes place

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through hospital Pharmacies. The prospect of improving and coordinating ordering of medications has been identified as a potential application. [1]

The National Medications Organisation (EOF) has implemented a bar coding system of medications since the 1st of January 2005. As of summer 2006 there will be additional batch coding for the purposes of pharmaco-vigilance follow-up. In August 2006 the launch of a pilot e-prescription project was announced, implemented by OPAD (Organisation for Health Care Provision to Public Servants) and utilizing the bar coding system of the National Medications Organisation, as already described under 3.3<sup>8</sup>.

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<sup>8</sup> <http://www.mohaw.gr/gr/theministry/nea/deltia.2006-08-10.2956407673>

## **9 General assessment**

The Greek regulatory framework is not yet ready for a full implementation of eHealth projects. The terms electronic health, electronic procurement or personal data are not mentioned in any of the legislative instruments of the Ministry of Health and Social Solidarity. However, a look at the general legal document that have been adopted or proposed in the last five years shows an attempt for compliance with the European directives [8]. The Greek data protection law provides specific provisions on health data and safeguards their processing by a health professional subject to the obligation of professional secrecy or to relevant codes of conduct. It also contains an important provision that exempts doctors and other persons rendering medical services, when they are bound by medical confidentiality or other obligation of professional secrecy, to obtain a permit when processing relates to health data.

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

There are currently two draft laws, one concerning the Quality and Safety of Healthcare Services and the National Health Information System and the other one for the establishment and operation of the primary health care. The eHealth of the Ministry of Roadmap sets out priorities and encompasses both strategy and action plans for the period 2006 – 2015 in the strategic areas of quality and safety of health services, which constitute the overriding strategic objectives. eHealth stands high in the agenda of the Ministry and significant efforts are made for the creation of a successful eHealth system in the next 8 years.

Eleni Kosta  
27 June 2008

## 10 List of legal and policy documents

- Law 1565/1939 (G.G. 16/A'/1939) for the code on the exercise of the medical profession, [Νόμος 1565/1939 (ΦΕΚ 16/A'/1939) «Περί Κώδικος ασκήσεως του ιατρικού επαγγέλματος»].
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- Law 2068/1992 (G.G. 118/A'/09.07.1992) for the ratification of the Council of Europe Convention for the Protection of Individuals with regard to automatic processing of personal data. [Νόμος 2068/1992 (ΦΕΚ 118/A'/09.07.1992) περί της ενσωμάτωσης στην εσωτερική νομοθεσία της Σύμβασης του Συμβουλίου της Ευρώπης για την Προστασία του ατόμου από την αυτόματη επεξεργασία προσωπικών δεδομένων].
- Law 2071/1992 (G.G. 123/A') Modernisation and organisation of the healthcare system – Article 47: Rights of the hospital patient. [Νόμος 2071/1992 (ΦΕΚ 123/A'), Εκσυγχρονισμός και οργάνωση συστήματος υγείας] – Άρθρο 47 Τα δικαιώματα του νοσοκομειακού ασθενούς.
- Law 2472/1997 (G.G. 50/A'/10.04.1997) on the Protection of Individuals with regard to the Processing of Personal Data. [Νόμος 2472/1997 (ΦΕΚ 50/A'/10.04.97) Προστασία του ατόμου από την επεξεργασία δεδομένων προσωπικού χαρακτήρα με ενσωματωμένες τις τροποποιήσεις], (in Greek) available online at [http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/LAW/NOMOTHESIA%20PROSOPIKA%20DEDOMENA/2472\\_97\\_MAY\\_08\\_EL.PDF](http://www.dpa.gr/pls/portal/docs/PAGE/APDPX/LAW/NOMOTHESIA%20PROSOPIKA%20DEDOMENA/2472_97_MAY_08_EL.PDF).
- Law 3144/2003 (G.G. 111/A'/08.05.2003) on social dialogue for the promotion of employment and social protection and other provisions. [Νόμος 3144/2003 (Φ.Ε.Κ. 111/A'/08.05.2003): Κοινωνικός διάλογος για την προώθηση της απασχόλησης και την κοινωνική προστασία και άλλες διατάξεις], (in Greek) available online [http://www.fle.gr/ergatika/Nomoi/Nomoi1980-2003/Nomos3144\\_03.htm](http://www.fle.gr/ergatika/Nomoi/Nomoi1980-2003/Nomos3144_03.htm).
- P.D. 38/2004 (G.G. 35/A'/09.02.2004) Adaptation of the Greek legislation to the provisions of Directives 2001/19/EC of the European Parliament and the Council of the 14<sup>th</sup> May 2001, 1999/46/EC, 98/63/EC, 98/21/EC, 93/16/EEC. [Π. Δ. 38/2004 (ΦΕΚ 35/A'/09.02.2004) Προσαρμογή της Ελληνικής Νομοθεσίας προς τις διατάξεις των Οδηγιών 2001/19/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 14ης Μαΐου 2001, 1999/46/ΕΚ, 98/63/ΕΚ, 98/21/ΕΚ, 93/16/ΕΟΚ, που αφορούν το επάγγελμα του ιατρού] (in Greek), available online at [http://www.dsnet.gr/Epikairothta/Nomothesia/pd38\\_04.htm](http://www.dsnet.gr/Epikairothta/Nomothesia/pd38_04.htm).

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- Law 3418/2005 (G.G. 287/A'/28.11.2005) on the Code of Medical Ethics. [Νόμος 3418/2005 (Φ.Ε.Κ. 287/A'/28.11.2005), Ιατρικός Κώδικας Δεοντολογίας], available online at [http://www.bioethics.gr/media/pdf/biolaw/human/code\\_of\\_practice\\_new\\_gr.pdf](http://www.bioethics.gr/media/pdf/biolaw/human/code_of_practice_new_gr.pdf)
  - Draft law for the establishment and operation of the primary health care, [Σχέδιο νόμου για την οργάνωση και λειτουργία του γενικού συστήματος πρωτοβάθμιας φροντίδας υγείας], available online at <http://www.mohaw.gr/gr/thefuture/prosexos/snpy2008b.pdf> and <http://62.103.163.130/gr/theministry/nea/deltio20080305.2>
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