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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE PORTUGAL

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European Commission
Directorate General Information Society

Brussels

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1 Documents

1.1 Applicable Documents

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

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
[RD3]	Recommendation of the Commission on eHealth interoperability, http://ec.europa.eu/information_society/activities/health/docs/policy/20080702-interop_recom.pdf
[RD4]	Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles)
[RD5]	European Observatory on Health Systems and Policies, Health Systems in Transition (HiT) country profiles, http://www.euro.who.int/observatory/Hits/TopPage
[RD6]	European Observatory on Health Systems and Policies, Patient Mobility in the European Union. Learning from experience, http://www.euro.who.int/observatory/Publications/20060522_4
[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/

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

2 Glossary

2.1 Definitions

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

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

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

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

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2.2 Acronyms

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

HiT.....	Health in Transition
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 Portuguese healthcare system

The main driver of the Portuguese healthcare system is that it has been built around a mix of public and private financing. A deep analysis is provided in the 2007 study written by Pedro Pita Barros and Jorge de Almeida Simões, Portuguese HiT country report published by the European Observatory on Health Systems and Policies
http://www.euro.who.int/Document/E90670.pdf (163p.)

From this report, we reproduce the following important observations:
"The Portuguese health care system is characterized by three coexisting, overlapping systems: the NHS; special public and private insurance schemes for certain professions (health subsystems); and private voluntary health insurance (VHI). The health system in Portugal is a network of public and private health care providers, each of them connected to the Ministry of Health and to the patients in its own way. Most of the population is entitled to choose among (or can use both) two health care insurers: NHS and VHI. The providers can be either public or private, with different agreements with respect to their financing flows, ranging from historically based budgets to purely prospective payments."
"The Portuguese health system is [note of the author: mainly] organized around an NHS, with some responsibilities delegated to regional bodies. The NHS is managed by the Ministry of Health. The internal organization of the Ministry is being restructured, in the context of a general reform of civil service in the country. Overlapping with the NHS are certain special public and private insurance schemes for certain professions (termed "health subsystems"), which are compulsory for groups of employees, and private VHI."
"The Portuguese NHS establishes the right of all citizens to health protection; a guaranteed universal right to health care (mostly free at the point of use) through the NHS and access to the NHS for all citizens regardless of economic and social background. In the Portuguese Constitution the NHS is defined as "universal, comprehensive and approximately free of charge".
"Since the mid-1990s, there have been several attempts to shift from retrospective to prospective payments for providers. Although the NHS health care units are paid according to yearly budgets, mid-year financial reinforcements made the payment system closer to historical cost budgeting and cost reimbursement than prospective budgeting. Since 2003, with the transformation of many NHS hospitals into (state-owned) corporate entities, the purchaser–provider split and the use of explicit contracts based on prospective payments have gained momentum. The contractual approach to hospital payments has also been recently extended to the remaining purely state-owned hospitals.
Patients in Portugal participate in health care financing via co-payments and co-insurance. For certain health care services delivered by NHS facilities the patient pays a certain fixed amount per use. For pharmaceutical products, a coinsurance scheme exists, for which the patient pays

a certain fixed proportion of the cost of the pharmaceutical. These systems work as third-party payer systems."
"Pharmaceutical products are distributed through community and hospital pharmacies. Only physicians can prescribe pharmaceuticals. The co-insurance rate varies depending on the therapeutic importance of the pharmaceutical product. For therapeutic groups with a generic equivalent, cost sharing has evolved to a reference pricing scheme. The reference price is set equal to the highest generic price for the pharmaceutical that has the same form and dosage, which must, nonetheless, be 35% below the price of the original branded product. The Portuguese health system has not undergone any major changes in terms of financing, despite the steady growth of public health expenditure since the early 1990s. On the other hand, many measures have been adopted to improve the performance of the health system. Measures since 2002 have included: PPPs for new hospitals; a change in NHS hospital management rules towards a more entrepreneurial approach and a more effective purchaser–provider split; promoting generic substitution of pharmaceuticals; liberalization of prices and entry onto the OTC market; administrative price reductions for pharmaceutical products; introduction of a reference pricing mechanism for pharmaceuticals facing competition from generics; regular updates of the co-payments for public health care services; reorganization of the public network of services (closure of delivery rooms in some hospitals, reshuffling of emergency departments, mergers of hospital management teams); definition of a national health plan; reform of primary care (creation of USFs); and creation of long-term care networks. Some of these measures have faced opposition from the (local) population, namely those related to the closure of health care facilities. There is an overall awareness, and concern, about the rise in health care expenditure in Portugal. Most of the reforms that have come into effect have done so too recently to measure any effects at the time of writing."

Please note also that there are institutional but private national initiatives on e-health.
The *Associação Portuguesa de Informática Médica* (Portuguese Medical Informatics Association), http://apim.med.up.pt/, is a non-profit-making association, created in 1979, whose aims are: Promote Medical Informatics applications to public health, medical practice, medical education and scientific research and its technical development. The Association act as a link between those interested in Medical Informatics as doctors, biologists, medical researchers, hospital administrators, etc.
ADT (Association for the Development of Telemedicine), http://www.cidadevirtual.pt/adt/, promotes the development of Telematic Platforms and Telemedicine Application in Portugal, by sharing and spreading information, aiming ultimately at the improvement of the healthcare serviced to the community. Its main objectives are:
- Promote and divulge the reality and perspectives of Information and Communication Technology applied to Health - by establishing the incentive to the collection and selection of information on technology, regulation and successful application and by creating conditions for its amply divulgation.
- Contribute and promote the study, debate and divulgation of the problems and techniques related to Telemedicine and Telematic applied to Health.

- Promote professional and scientific improvement of its members - by stimulating research and development of the adequate mechanisms for the effective acquisition and transference of knowledge.
- Promote intellectual, cultural and social gathering, as well as the exchange of experiences among its members - reinforcing and increasing the net of individuals and entities.
- Promote and establish the interchange of activities and services among similar associations, national and foreign, through the participation in international meetings, information exchange and cooperation in common projects.

3.2 Use of ICT in the Portuguese healthcare sector

There are no comprehensive studies on the use of ICT by Portuguese specialists, hospitals or pharmacies.
However, according to the 2007 study of the use of ICT by *general practitioners* in Portugal 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 we may take the following :
"Portugal can be regarded as an average eHealth performer in the EU27. In terms of infrastructure, Portugal is on par with the EU27 average concerning the use of computers and the use of the Internet. Broadband connections are however slightly less common in Portugal than in Europe on average.
When it comes to the actual use of eHealth applications, Portugal displays its best results for the use of computers for consultation purposes (64%), the use of Decision Support Systems (60%) and the storage of administrative patient data 74%). No shares however exceed European averages. The transfer of patient data is much less common, with regard to these indicators Portugal has to be considered one of the laggards.
A lack of infrastructure may also be the reason for the fact that up until now only very few GP practices transfer administrative and medical patient data. The Portuguese government has become aware of this issue and is currently taking steps to facilitate data exchanges by setting up a national health information network.
The Portuguese electronic identify card (eID) will replace five existing cards and the data will be stored in the National Data Centre. Another future activity will be the implementation of a nationwide ePrescribing scheme."

3.3 National eHealth strategy

The June 2007 report "eHealth strategy and implementation activities in Portugal" (Authors: José Luís Monteagudo and Oscar Moreno): http://www.ehealth-era.org/database/documents/ERA_Reports/Portugal_eHealth-ERA_country_report_final_01-06-2007.pdf provides an updated overview of the eHealth strategies and implementation in Portugal.
We consider that we may provide the following information of the said report:

"E-Health is considered a national priority at the National Action Plan for Information Society. The main objective is to use the ICT to place the citizen at the centre of the health system, while increasing the quality of the services provided, increasing the efficiency of the system and reducing costs.
The healthcare Action Plan for the development of the information society intends to reach three great strategical objectives:

- To provide a bigger quality of service to the users;
- To reduce costs of the national health system increasing the efficiency levels;
- To guarantee a better procedure efficiency and management.

These objectives are supported by three action lines within the eHealth policy:

- Improvement of the Health Information networks: it is basic for the improvement of the quality of life of the citizens. Encouraging the sector with the tools (equipment, software and services) which guarantee a communication backbone, capable to support the information exchange among all the health services and the implementation of a new added value set of services on this network which improve it.
- On-line health services: to improve communication between patients and doctors, for example, use new applications based on the Internet and mobile services, continuous monitoring of some chronic illness (diabetes, high blood pressure, obesity, drug dependency), medication and treatment follow-up and for support the patient's family.
  Three great priorities had been defined to materialize the concept of the services of health in line:
  1º priority - To offer new canals of access to the patient
  2º priority - To develop an integrated system of hospital network management
  3º priority - To implement the electronic health record at health institutions
- The user/patient card: use of the patient card to provide the SNS with personalized and more useful information about an efficient care for the patient."

For this matter, please see:
Health Portal of the Ministry of Health
http://www.portaldasaude.pt
Health Directorate General
www.dgs.pt
www.infosociety.gov.pt

3.4 Regulatory framework for patients' summaries

The only guideline regarding patient summaries is that all clinical information and identification data must be included in the clinical file (Patient Rights and Duties Chart - *Carta dos Direitos e Deveres dos Doentes*).

3.5 Regulatory framework for telemedicine

There are no specific provisions in Portugal with regard to telemedicine. We have access on an informal basis to a decision of the Order of Physicians that opted not to make a clear decision regarding telemedicine (relevant data of the data, such as the name of the applicants and the date of issuance, was blanked). This document after having provided that there are no legal or deontological rules and that the "more correct" solution would be to wait for deontological rules, opted to provide some consideration on guidelines are to be followed, such as: (i) observe the guidelines of the Permanent Committee of European Physicians; (ii) patients must be preferably be personally assisted and telemedicine should be limited to the situations where the physicians is not able to be on site; (iii) when a patient opts for telemedicine, the assistance must be made by its usual doctor; (iv) secrecy and other registration data must be observed; (v) the practice of telemedicine is only allowed by physicians inscribed on the Bar.

From a strict point of view, we tend to consider that there are no major legal obstacles to practice telemedicine if all legal general requirements regarding the rights and duties of professionals and patients are met.

Please note also that ADT (Association for the Development of Telemedicine) has a major goal to promote the development of Telematic Platforms and Telemedicine Application in Portugal.

3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions but an administrative rule enacted by the Government will try to develop the use of e-prescriptions on a comprehensive way. Please see Section 8.

3.7 Overview of relevant legislation

No legal framework has been yet enacted. The National Health Plan defines the guiding principles of healthcare provision in Portugal. All the projects have to be implemented within the scope of the mentioned Plan. Regulatory measures with a bearing on this field are limited to data protection laws and publicity and medication marketing guidelines.

The latest governmental initiative was the National Action Plan for the Information Society, which addresses a number of eHealth issues. The improvement of the communication infrastructure in the health sector, the enhancement of online health services and the introduction of a user card for patients are the main objectives of the Portuguese eHealth policy.

In more detail, in June, 2007 the Portuguese government published the Administrative Order n.º 711/2007, 11 June, and RCM n.º 96, 27 July, 2007, authorizing all the national health services launching public tenders in order to buy informatics systems to guarantee in all those services the implementation of an integrated solution of electronic prescriptions, invoicing and administrative management.

4 Regulatory framework for the healthcare profession

4.1 Legal conditions for the practice of healthcare

The practice of medicine is regulated by Decree-Law Nr. 282/77, 5 July, which defines the statute of the Portuguese medical association (*Estatuto da Ordem dos Médicos*). To exercise Medicine, physicians need to hold a legal diploma of physician and be members of the national Order of Physicians (*Ordem dos Médicos*). Only physicians with a degree conferred by a national university or by a foreigner university recognize for the purpose in Portugal, can be members of the Order of Physicians, independently of their nationality.
The practice of medicine in Portugal is subject to the following requirements:

- Possession of the legally required diploma: diplomas awarded in other EU Member States are assimilated in accordance with the provisions of Council Directive 75/363.
- Inscription on the list of the Order of Physicians.

There is not a legal definition of "act of medicine", although a Project of law has already been approved by the Parliament but the President of the Republic cancelled it.

4.2 Control over the practice of medicine

According to the Decree-Law Nr. 282/77, 5 July, practice of medicine in Portugal is supervised by the Other of Physicians (*Ordem dos Médicos).* That supervision includes all physicians that practice or who have practiced clinical medicine, as said it is not allowed to practice medicine without being inscribed on the list of the Order.
The most important function of the mentioned is to ensure observance of the rules of professional conduct for medical practitioners and the upholding of the reputation, standards of discretion, probity and dignity of the members of the Order.
Organs of the Physicians Order with disciplinary competences are: (i) National Council of Discipline (*Conselho Nacional de Disciplina*); (ii) Regional Disciplinary Council (*Conselho Disciplinar Regional).*

4.3 Professional liability

Notwithstanding the disciplinary liability (previously mentioned), physicians are subject to civil liability when an obligation is not fulfilled. Obligations originate either from a contract or from tort and are subject to general Civil Code (*Código Civil)* rules.
Supreme Court is consistently considering that the practice of medicine constitutes a provision of services relationship and thus it is mainly within the scope of this responsibility that the malpractice of medicine is civilly punished (even if the contractual relationship is not admitted, in any case the willful or negligent malpractice of medicine or omission of practice is condemned). Thus, in this case patients are granted with the right of being indemnified regarding the damages that have suffered (please note that courts, in general, settle low indemnifications regarding non-patrimonial damages or real losses).

4.4 Professional secrecy

The roots of medical confidentiality reach back to the Hippocratic oath Confidentiality of any medical record is covered by Constitutional and Civil law, as well deontological rules. Physicians are obliged to maintain medical secrecy and to keep secret all the information direct or indirectly acquired included their visits done or programmed. The secret obligation extends to the content of eventual conversations between physicians about patients information or other sources. Medical secrecy exists even if the medical service is not remunerated. The duty of medical secrecy is not limited to physicians who are providing healthcare to the patient, but also to the others physicians of the team and their directors or managers. A medical secret can only be revealed in the event of defense of dignity, honor or interest of the patient or physician, in those cases the physician can only reveal the necessary information unless authorization of the Medical Order. There is no professional secrecy if the patient discloses the information.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 1991, Portugal has general legislation protecting the individual with regard to automatic processing of personal data. The Law 10/91 has been revoked in 1998, in order to transpose the provisions of the European Directive 95/46/EC.
Generally speaking the Portuguese data protection law is very similar to the European directive. The Portuguese legislator has been very reluctant to make a maximum use of his possibilities to specify or to further detail the provisions of the Directive. The major guidelines are the following:

1. The relevant legislation concerning this matter is Law 67/98, of 26 October 1998 (Personal Data Protection Law, "**PDPL**"), which implemented and transposed in a quite literal way the 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 the free movement of such data, into the Portuguese legal system.
2. According to PDPL, personal data shall mean any information, regardless of the medium involved, including sound and image, relating to an identified or identifiable individual ("employees" or "data subject"). This means that health data are personal data and accordingly, protected by data protection law.
3. As a general rule, data subjects from which personal data are processed must be provided – in an express, specific and unequivocal manner - with certain prior information concerning the processing of their personal data, namely relating to the existence and purpose of the personal data file or data processing, the identity and address of the controller (LDCP), the recipients or categories of recipients and the possibility of exercising the rights of access, rectification, cancellation and opposition.
4. Please note also that personal data must be: (a) processed lawfully and with respect for the principle of good faith; (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; (c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed; (d) accurate and, where necessary, kept up to date; adequate measures must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified; (e) kept in a form which permits identification of their subjects for no longer than is necessary for the purposes for which they were collected or for which they are further processed. This means that all processing within the scope of e-health must be submitted to these principles.

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

The transposition of art. 8 of Directive 95/46/EC has been done by Article 7 of PDLP. This article covers regards contains a provision on sensitive data, which includes the health data, among other types of data.

As mentioned, Article 7 of PDLP regulates the processing of sensitive data, which includes health and genetic data. The wording is the following:

"1 - The processing of personal data revealing philosophical or political beliefs, political party or trade union membership, religion, privacy and racial or ethnic origin, and the processing of data concerning health or sex life, including genetic data, shall be prohibited.

2 - The processing of the data referred to in the previous number shall be permitted by a legal provision or by the authorisation of the CNPD when, on important public interest grounds, such processing is essential for exercising the legal or statutory rights of the controller or when the data subject has given his explicit consent for such processing, in both cases with guarantees of non-discrimination and with the security measures provided for in Article 15.

3 - The processing of the data referred to in 1 shall also be permitted when one of the following conditions applies:

(a) When it is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent;

(b) When it is carried out with the data subject's consent in the course of its legitimate activities by a foundation, association or non-profit seeking body with a political, philosophical, religious or trade union aim and on condition that the processing relates solely to the members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects;

(c) When it relates to data which are manifestly made public by the data subject, provided his consent for their processing can be clearly inferred from his declarations;

(d) When it is necessary for the establishment, exercise or defence of legal claims and is exclusively carried out for that purpose.

4 - The processing of data relating to health and sex life, including genetic data, shall be permitted if it is necessary for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, provided those data are processed by a health professional bound by professional secrecy or by another person

also subject to an equivalent obligation of secrecy and are notified to the CNPD under article 27 [NOTE: it means, registration with the Data Protection Authority], and where suitable safeguards are provided."

Furthermore, it is expressly set out that the processing of sensitive data (as mentioned, this definition includes health data) is subject to specific security requirements.
In fact, Article 15 provides that:

"1 - The controllers of the data referred to in Articles 7 (2) and Article 8 shall take appropriate measures to:

a) Prevent unauthorised persons from entering the premises used for processing such data (control of entry to the premises);

b) Prevent data media from being read, copied, altered or removed by unauthorised persons (control of data media);

c) Prevent unauthorised input and unauthorised obtaining of knowledge, alteration or elimination of personal data input (control of input);

d) Prevent automatic data processing systems from being used by unauthorised persons by means of data transmission premises (control of use);

e) Guarantee that authorised persons may only access data covered by the authorisation (control of access);

f) Guarantee the checking of the bodies to whom personal data may be transmitted by means of data transmission premises (control of transmission);

g) Guarantee that it is possible to check *a posteriori*, in a period appropriate to the nature of the processing, the establishment in the regulations applicable to each sector of which personal data are input, when and by whom (control of input);

h) In transmitting personal data and in transporting the respective media, prevent unauthorised reading, copying, alteration or elimination of data (control of transport).

2 - Taking account of the nature of the bodies responsible for processing and the type of premises in which it is carried out, the CNPD may waive the existence of certain security measures, subject to guaranteeing respect for the fundamental rights, freedoms and guarantees of the data subjects.

3 - The systems must guarantee logical separation between data relating to health and sex life, including genetic data, and other personal data.

4 - Where circulation over a network of the data referred to in articles 7 and 8 may jeopardise the fundamental rights, freedoms and guarantees of their data subjects the CNPD may determine that transmission must be encoded."

5.3 Information and access rights of data subjects

Article 11 enacts a specific provision regarding the right to access of the data subjects.

"1 - The data subject has the right to obtain from the controller without constraint at reasonable intervals and without excessive delay or expense:

(a) Confirmation as to whether or not data relating to him are being processed and information as to the purposes of the processing, the categories of data concerned and the recipients or categories of recipients to whom the data are disclosed;

(b) Communication in an intelligible form of the data undergoing processing and of any available information as to their source;

(c) Knowledge of the logic involved in any automatic processing of data concerning him;

(d) The rectification, erasure or blocking of data the processing of which does not comply with the provisions of this Law, in particular because of the incomplete or inaccurate nature of the data;

(e) Notification to third parties to whom the data have been disclosed of any rectification, erasure or blocking carried out in compliance with (d), unless this proves impossible.

2 - In the case of the processing of personal data relating to State security and criminal prevention or investigation, the right of access may be exercised by means of the CNPD or another independent authority in whom the law vests verification of compliance with legislation on the protection of personal data.

3 - In the cases provided for in 6 above the right of access is exercised by means of the CNPD, securing the constitutional rules applicable, in particular those guaranteeing freedom of expression and information, freedom of the press and the professional independence and secrecy of journalists.

4 - In the cases provided for in (2) and (3), if communication of the data might prejudice State security, criminal prevention or investigation and freedom of expression and information or the freedom of the press, the CNPD shall only inform the data subject of the measures taken.

5 - The right of access to information relating to health data, including genetic data, is exercised by means of the doctor chosen by the data subject.

6 - If the data are not used for taking measures or decisions regarding any particular individual, the law may restrict the right of access where there is clearly no risk of breaching the fundamental rights, freedoms and guarantees of the data subject, particularly the right to privacy, and when the data are used solely for purposes of scientific research or are kept in personal form for a period which does not exceed the period necessary for the sole purpose of creating statistics."

This means that the Portuguese legal framework provides a specific rule regarding the contact of the data subject with the controller, which must only be carried on by means of a health professional (no. 5).

Furthermore, we must also stress that all these rules shall apply in the implementation of e-health solutions.

5.4 Final remark

Please note that there are no court decisions analysing the scope of e-Health and personal data issues, nor there are updated relevant texts on this matter.

6 Rights and duties of healthcare providers and patients

6.1 Scope of the law

The duties of physicians are specifically ruled by the Statute of the Physicians Order and the Deontological Code
The right to healthcare is regulated in the article 64 of the Constitution,, containing a set of fundamental interests, such as the human dignity, the equity, ethics and solidarity.
The health legal framework of the contains more specific rights, namely in the Base Health Act (*Lei de Bases da Saúde - Lei n.º 48/90, de 24 de Agosto*) and in the Statute of the Hospital (Decree-law no. 48375, of 27 April 1968 - *Decreto-Lei n.º 48 357, de 27 de Abril de 1968*).
Furthermore, the principles around all these acts and rules lead to the enactment of the Patient Rights and Duties Chart (*Carta dos Direitos e Deveres dos Doentes*).

6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is in the Patient Rights and Duties Chart, the patient has the duty to promote is own health and the health of his community, and should, as well respect and co-operate with the all the health professionals. The only practical legal meaning would seem that a health professional who is sued by a patient, may seek a defense in the invocation of patient's non-co-operative behavior.

6.3 Right to quality care

There is only general guidance. Patient Rights and Duties Chart sets out that the patient must be treated by the respect of the human dignity and has the right to the assistance of friends and family and the spiritual assistance must also be provided if required by the patient.
Furthermore, in general, the Deontological Code also imposes to be provided high professionalism in the provision of healthcare treatments and respect to the health of patients.

6.4 Right to free choice

This right is not specifically referred, nevertheless according the Patient Rights and Duties Chart the patient has the right to freely ask for a second opinion concerning his health.

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. This information must be provided in a clear way, taking in account the personality, the education and clinical and psychical conditions of the patient.
More specifically, the information must contain all elements regarding the diagnosis (type of disease), prognostics (evolution of the disease), treatments to carried on, related risks and alternative treatments.

The patient is also entitled not to be informed about the state of health, but this wish must be expressly mentioned by the patient. In this case the patient has also the right to indicate another person to be briefed about his state of health.

6.6 Right to give consent

The patient has the right to choose between giving or not giving his consent prior to any medical act provided by a health professional. The consent must be "free and well informed", and only applicable to the concrete act. Consent must be given expressly, except in emergency cases, and in cases of legal incapacity, where the patient must be exercised by his legal representative. Patients can change their decisions. Patients have the right to refuse or withdraw consent for any service.

6.7 Rights related to the patient's medical record

Patient Rights and Duties Chart expressly sets forth that patient has the right to access to medical records of his clinical file (according to this rule, all clinical information and identification data must be included in the clinical file) – the patient would always have the right to access his medical record under the general personal data rules (please see Section 5.3. of this report). The information must be provided in a clear way.

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. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent. Private life of the patients must only be investigated up to the limit required necessary to the diagnosis or the treatment and the patient authorizes it.

6.9 Right to representation in case of incompetence

The law does not contain a specific provision of this matter. However, from the Civil Code rules, 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. Obviously that minor patients should be involved in exercising his rights, bearing in mind his age and level of maturity. Minor patients who are deemed capable of reasonably grasping their situation may exercise their rights on their own behalf.

7 Identity management in the health sector

It is not expected to be implemented a co-ordinated identity management system for the Portuguese healthcare sector, as the implementation of the eIDM project is to include in the card attributes the identities of patients. The driver is then to use the general Portuguese eIDM system in the healthcare sector. The information in this chapter is based on our IDABC-report referenced under [RD9].

7.1 Overview

The most significant e-IDM system in Portugal is based on the Personal Identity Card (*Cartão do Cidadão*), to be granted to Portuguese Citizens from the age of 6 and up. A second relevant e-IDM is the project of the Electronic Passport.
The Personal Identity Card has been launched in February 14, 2007. It has only been implemented in Azores and it is expected to cover all Portuguese territory by the end of 2008. However, the roll-out processing will take until 2012 to have full coverage and to replace the paper token. In the areas that are covered, the issuance of the Personal Identity Card is mandatory. The ID card costs 12 euros.
This card will only be distributed by the same location where the ID hard copy document is provided: the Local Civil Registry and Citizen's Shops ("*Lojas do Cidadão*").
This card, on its roll-out phase, shall be a mandatory electronic identity card that is intended to identify all Portuguese citizens (as well as Brazilian citizens covered by the Safe Harbour Treaty) from the age of 6 and up.
Detailed information is available through the official Portuguese eID website (http://www.cartaodecidadao.pt/).
The card contains 5 numbers ("personal identification number", social security number, tax number voters card number, and health user number) and a chip holding two certificates: one for authentication purposes, and one for qualified signatures. This card will allow multichannel identity authentication, namely in presence or trough the Internet, allowing the citizen to identify himself electronically and to dispose of a legally valid electronic signature.
The system is closely linked to the Instituto da Tecnologia da Informação na Justiça (*ITIJ*) – *Sistema de Gestão do Ciclo de Vida de Cartão do Cidadão* - , which contains a key set of authentic attributes for citizens registered in it.
The attributes stored in the authentication certificate of the eID card are obtained directly from the *ITIJ*, being the other data collected from: (a) the Identification Services (*Serviços de Identificação Civil da Direcção-Geral do Registos e Notariado*) in relation to the "identification number"; (b) regarding the tax number, from the Tax authorities (*Direcção-Geral de Contribuições e Impostos*); (c) regarding the health number, from the Ministry of Health (*Ministério da Saúde*); (d) data referring to the Social Security, from the Social Security (*Segurança Social*).

The eID card will function as a unique card for Portuguese citizens, but it contains several numbers, due to constitutional restraints in adopting one unique number to Portuguese citizens.
As mentioned tokens include also the paper federal token in the areas where the e-Card is not implemented.

7.2 The User Card (Cartão de Utente): the patient identifier

Prior to the introduction of the national eID card and the use of it for the identification of the users within the Health National System, it has been launched the User Card. The User card is a smart card with a bank card format, without a photo of the bearer.
The following information is printed visibly on the card: name, number of the user (according to the Portuguese Constitution, a unique number is not allowed and thus the health user number is autonomous) and the Health Centre.
The chip on the card contains the same information, as well as medical benefit information (if the user is exempted of any medical national tax), other non-clinical information but related with the use of the national health system by the patient, such as consultancies, use of emergencies).
The card is used by hospitals (administrative staff) to verify the public medical insurance status The card is not secured with a specific PIN-code, since the information can only be read through the hospital readers.
In the future, it expected that the eIDM (which contains also the health user number) may replace this card.

7.3 Authentication of healthcare professionals

Healthcare professionals (doctors) are inscribed in the Order of Physicians (*Ordem dos Médicos* – please see the portal www.ordemdosmedicos.pt). This register contains information about the diploma and the specialization of a health care provider identified through his medical personal card (*cédula professional)*. This is a mandatory requirement. This register is available online (www.ordemdosmedicos.pt/?lop=listamedicos) and the services of the Order of Physicians are also used as a validated authentic source, when a certificate must be issued in what concerns to the identification of doctors.
These professionals have also a personal card (size of a credit card), but it does not contain any electronic device. This card only have the following data: name, professional name, data of registration, medical speciality. No tokens, password or user name, or obviously, digital certificate is included in. The validity of this card is 5 years.
Accordingly, this authentication card is not able to be of use in an electronic platform.

8 Electronic prescription

According to the Portuguese law, medical prescriptions need to be signed and dated by the physician and that it should indicate, as far as possible, the way the medicine should be used. No specific law has been regarding e-prescriptions. Nevertheless, as already mentioned in June, 2007 the Portuguese government published the Administrative Order n.º 711/2007, 11 June, and RCM n.º 96, 27 July, 2007, authorizing all the national health services launching public tenders in order to buy informatics systems to guarantee in all those services the implementation of an integrated solution of electronic prescriptions, invoicing and administrative management.

Please note also that many electronic prescriptions have been implemented. For instance, in January, 2005, the Portuguese Government has announced a pilot of electronic prescriptions in the public hospital Pedro Maria Santos in Portalegre, with a view to generalize the system to the entire country by the end of the year. The main goal was that the electronic prescription system would be progressively phased-in throughout the Portuguese territory during 2005. Portalegre is a small city in the interior south of the country with a low level of population but with a high number of pharmacies provided with their own informatics systems. At the time, as in our days, the adoption of e-prescriptions was part of a wider health policy that aims at rationalizing healthcare and the use of medication by implementing ICT applications and promoting generic medication.

In the centre littoral of the country, in the city of Aveiro by investing in new systems, networks and online services the regional healthcare public services have gained new capabilities, with a strong impact on the efficient access to the healthcare system, for example there are already implemented tele-diagnostic The services, a regional portal of healthcare services (www.rdsr.net; www.rtsaude.pt) and a distributed clinic registering service

For that purpose it was develop and implemented the “Rede Telemática da Saúde” (RTS) a telematic health network, in order to improve clinical communication and interaction between healthcare institutions. The project partners include Hospital Infante D. Pedro (the project leader, in Aveiro), Hospital Distrital de Águeda, Sub-Região de Saúde de Aveiro (responsible for 19 primary care centres) and University of Aveiro, as the technological partner. The main idea behind the project can be summarized by the slogan “Connected for a better healthcare”. In fact, the project aims at promoting the secure electronic access to clinical information stored in the different healthcare providers to all credentialed professionals. At the same time, citizens will also be able to manage their health issues over the RTS telematic platform.

In our days, approximately 34% of the prescriptions are electronic prescriptions, and they are issued in 18 Health Sub-Regions, located across the country.

The goal is also to reinforce the 2006 process of the certification process for e-prescription applications used by private physicians and other institutions in order to enable their integration in the national e-prescription flow.

9 General assessment

The National Health Plan defines the guiding principles by which institutions within the Ministry of Health, other bodies in the health sector (state, private and social welfare institutions) and other relevant sectors can assure, or contribute to, the achievement of health gains between 2004 and 2010.
This is a general guideline document. All of the ehealth projects are subject to this mere guideline act. In fact, no Portuguese regulatory framework has been enacted regarding e-health, with the exception of an administrative rule that tries to implement in a comprehensive way e-prescription proceedings.
Portugal is already facing the implementation of many projects within the scope of health portals, telephone help-lines, telematic solution, eprescription.
Furthermore, the eID (and even the NHS patient card – User's card) is already contains some properties allowing the development of e-health platforms.
On the other side, the identification card of healthcare professionals must be subject to a deep reformulation as it is merely a paper document without any electronic capability.
Notwithstanding, e-health projects and solutions are an important driver to the development of the health national system and it is seen as a relevant approach to lead to development of more efficient healthcare treatment within the public service.

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