

SMART 2007/0059

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Study on Legal Framework of Interoperable eHealth in Europe

National profile Italy

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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

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	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)

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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/EC, 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

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sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC.

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

2.2 Acronyms

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

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HiT..... Health in Transition

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OCSP..... Online Certificate Status Protocol

PKI..... Public Key Infrastructure

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NRN..... National Register Number

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SIS..... Social (security) Information System

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SSCD Secure Signature Creation Device

SSIN..... Social Security Identification Number

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TTP..... Trusted Third Party

3 Introduction

3.1 General overview of the Italian healthcare system

3.1.1 The State services in the healthcare sector

A comprehensive overview of the Italian healthcare system can be found in the Italian HiT country report published by the European Observatory on Health Systems and Policies: “Health Care Systems in Transition”. Although the report was published in 2001, its contents are still valid for the most part. Unless otherwise indicated, all passages in quotation marks are taken from such source. Other online general information can be found at the Ministry of Health portal, at URL <http://www.ministerosalute.it/ministero/sezMinistero.jsp?label=principi>

“Italy's health care system is a regionally based national health service that provides universal coverage free of charge at the point of service”.

The system is organized at two levels: national and regional.

“The national level is responsible for ensuring the general objectives and fundamental principles of the national health care system. Regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefit package through a network of population-based health management organizations (local health units) and public and private accredited hospitals”.

To be more precise, it is up to the central institutions to rule on the basics of the healthcare system: for example, the minimum level of civil and social rights that citizens shall be granted. As per article 117, § 2, letter m) of the Italian Constitution, the protection of public health is shared between the State and the Regions. The latter can issue laws within the framework of the basic principles established by State legislation.

The Ministry of Health (URL: www.ministerosalute.it), through its departments and services, accomplishes the following main functions:

- healthcare planning;
- healthcare financing;
- framework regulation;
- healthcare expense monitoring. As per Law 23 December 1998, no. 448, Regions and autonomous Provinces shall send to the Ministry of the Health, via the National Agency for Regional healthcare services, all information about such drugs sold in chemist's where the costs are borne by the State, with the exclusion of therapeutic oxygen;
- general governance of the IRCCS – Istituti di Ricovero e Cura a Carattere Scientifico (National Institutes for Scientific Research);
- central role in the SSN – Servizio Sanitario Nazionale (Italian National Health Service, or NHS).

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In the Italian framework NHS refers to the complex of healthcare activities performed by the State and the local entities for all citizens, regardless their age, race, gender, income and work. It was established with Law 833/78.

“The Ministry of Health, under its planning function, is responsible for proposing to the Treasury the level of public funding to be dedicated to health care. Through the national health planning process, the Ministry of Health suggests how resources should be allocated among levels of care (hospital care, district and primary health care and community health care) to address the population needs which are surveyed in the annual national health status report.

“The Ministry of Health is also responsible for technically regulating healthcare activities in various areas: managing human resources at NHS institutions; optimizing the workforce in the NHS; maintaining disease prevention programmes with a nationwide focus; promoting nutritional health; and promoting veterinary health through the general regulation of a network of ten experimental zooprophyllactic institutes. Italy is one of the few countries in which the national health service manages veterinary care”.

“The Ministry of Health, through a specific department, is also responsible for generally coordinating the activities of the National Institutes for Scientific Research (IRCCS), a network of 16 public and 16 private research hospitals. These hospitals use mainly public funding for basic and clinical work and research and for experimenting with new organizational solutions for hospitals and other health care settings.”

Dealing with the Ministry of Health, it is necessary to mention two public bodies working closely with the Ministry: Consiglio Superiore di Sanità (National Health Council) and Istituto Superiore di Sanità (National Institute of Health).

The National Health Council is the scientific and technical consulting organ of the Ministry of Health. It is regulated by legislative Decree 30 June 1993, no. 266 and Ministry Decree 6 August 2003, no. 342.

The National Institute of Health is the main institution for scientific and technical research, control and advice in public health”.

3.1.2 Regional services in the healthcare sector

Regions are in charge of the organization of healthcare structures and services, and shall effectively provide the level of services known as LEA - Livelli Essenziali di Assistenza (essential levels of assistance). To that end, Regions control the local health units (aziende sanitarie locali – ASL), which shall guarantee homogeneous healthcare assistance in any and all regional territory. Public hospitals (aziende ospedaliere) are also controlled by the Regions.

Regions assist in national decisions by taking part in a permanent conference, called “Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome” (permanent conference for the relationships between State, Regions and Provinces).

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“Regional governments, through their departments of health, are responsible for pursuing the leading national objectives posed by the National Health Plan at the regional level. Regional health departments are required to guarantee the benefit package to be delivered to the population through a network of population-based health care organizations (local health units) and public and private accredited hospitals. They are responsible for legislative and administrative functions, for planning health care activities, for organizing supply in relation to population needs and for monitoring the quality, appropriateness and efficiency of the services provided. The regional level has legislative functions, executive functions as well as technical support and evaluation functions”.

“The regional health departments in some regions provide technical support directly to the local health units and to public and private hospitals. Other regions have formed a regional agency for health which is responsible for assessing the quality of local health care and providing technical and scientific support to the regional health departments and to the local health units. The regional agencies also provide technical support to the regional health departments during the planning process to assess population needs, to define the range of services to be supplied to address these needs, and to assess the quality of services provided by single providers in the region”.

At local level, it is necessary to also mention independent private accredited healthcare providers.

3.2 The use of ICT in the healthcare sector

According to a recent study of the European Commission Information Society and Media Directorate titled “General Pilot on eHealth Indicators. Benchmarking ICT use among GPs in Europe 2007”, at URL: http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/gp_survey_final_29_country_brief_s.zip.

Italy is among the average eHealth performers in the EU27. This concerns both the availability of ICT infrastructure (computer, Internet) and the use of ICT for different eHealth related purposes. In terms of infrastructure, Italy comes very close to the averages found in the EU27 in this regard: 86% of the Italian GPs use a computer; a figure which puts the country on a par with its European neighbours. Currently 71% of the Italian GPs (GPs) are connected to the Internet and broadband connections can be found in almost half of the practices (49%).

With regard to the use of eHealth applications, Italy achieves results that correspond to or even exceed European averages. The best results are achieved for the storage of administrative data and the use of a computer for consultation purposes. The storage of electronic patient data is comparatively common in Italy. At least one type of individual medical data is stored in 83% of GPs practices.

A computer is available in the consultation room in 84% of Italian GPs. Nearly all of these GPs actually use the computer for consultation purposes with the patients (81%). In other EU27 countries this ‘availability versus use’ gap is sometimes as high as 50% or higher. 69% of Italian GP practices use a Decision Support System (as compared to 50% on average in the EU27). In Italy the exchange of electronic patient data is not yet well established. Only 3% of Italian GPs exchange administrative data with other care providers. This compares to an average rate of 10% reached by the EU27.

With only 1% of GP practices that exchange administrative data with reimbursers, Italy scores below the EU average of 15%. Frontrunner countries in this regard are Denmark, the Netherlands and the United Kingdom, but even here not more than one out of two practices uses this feature.

Only 8% of GP practices receive results from laboratories. This is however by far the most frequent use

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type in the EU27: on average 40% of European practices receive laboratory results via network connections. 7% of Italian practices exchange medical patient data with other carers. With regard to this indicator Italy comes very close to the EU average. Electronic exchange of prescriptions, commonly referred to as ePrescribing, is practised by 1% of the practices in Italy. ePrescribing can be regarded as a reality only in three Member States: Denmark, the Netherlands and Sweden. Apart from these countries adoption levels are never higher than 5%.

An appropriate ICT infrastructure in the practice lays the ground for different eHealth use cases (such as storage of patient data, ICT and so forth). It is therefore the baseline from which a European GP can start their professional activities in the eHealth domain. ICT infrastructure as understood here entails the availability of one or more computers in the practice; a connection with the Internet; and the availability of a broadband connection. 86% of GP practices in Italy are equipped with one or more PCs. This result is close to the EU27 average and puts Italy on a par with 8 other EU countries where computer availability rates of 80-90% are reached. All in all 24 countries show a penetration rate of more than 75%, a fact that clearly indicates that computers have arrived in EU GP practices. They are becoming more and more an essential and part of the practice.”

3.3 National eHealth strategy

In Italy a legislation providing a comprehensive national strategy on eHealth has not been issued, while some initiative based on State-Regions co-operation have been activated (see the following). Such a situation is mostly due to the fact that, as a result of the Constitutional reform of 2001 (see Law 18 October 2001, no. 3), the effective implementation of services and structures in the healthcare sector is in power of the Regions. Here the State shall only fix general principles, like the “LEA”, the already mentioned essential levels of assistance, while it is up to the Regions to develop and manage the healthcare providers (ASL, hospitals, private accredited healthcare providers) and the healthcare projects. Indeed, in the present context, a few regional eHealth programmes have been established, based on regional laws, which can be seen as models for other Regions. Three of them will be addressed in the following §§ 7.2, 7.3, 7.4 of the present work.

That said, it has been announced by the present Government that in the next future a national legislation on eHealth will be approved, within the boundaries of the general health principles. As a matter of fact, many political efforts currently appears to be directed to the field of the electronic healthcare, which show a substantial interest in that field.

It must be added that State laws in other areas also affect the healthcare sector, such for instance the remarkable efforts which have been carried out in the area of legislation on digitalization. Notably, some legal instruments established in this broad area, like “firma digitale” and “carta nazionale dei servizi”, are the basic elements on which the already regional eHealth programmes are based on.

Further, relevant accomplishments at national level have been carried out as for the rules to be observed in the electronic processing of personal data, a field which clearly involves the EHRs.

This framework is confirmed by an overview of the Italian eHealth policy recently (June 2007) published in the context of the ERA project: see G. Mercurio, A. Rossi Mori, P. Agnello, M. Mangia, M. Mazzeo, “eHealth strategy and implementation activities in Italy” (at URL: http://www.ehealth-era.org/database/documents/ERA_Reports/Italy_eHealth-

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[ERA Country Report final 01-06-2007.pdf](#)).

Quoting from this report, here are in brief some specific initiatives in eHealth sector promoted either directly by State or by a State-Region co-operation. Such initiatives are the following: NSIS, “Cabina di Regia” established by the Ministry of Health, TSE - Tavolo permanente per la Sanità Elettronica

NSIS – Nuovo Sistema Informativo Sanitario (<http://www.nsis.ministerosalute.it/>)

“In February 2001, the Permanent Committee for political issues between central and regional authorities (*Conferenza Stato-Regioni*) endorsed an agreement to develop the New National Healthcare Information System (*NSIS*) – a common tool to achieve governance objectives, overseeing and monitoring the Fundamental Levels of Healthcare Services.

The strategic framework of NSIS defines the general lines and the progressive stages of development of the system’s various components. The patient and the care delivery structure are identified as central information entities. Therefore, the main objectives call for the development, at national level, of:

- an integrated system of individual healthcare information, making homogeneous information available for the individual healthcare events, and making it possible to ascribe each event to the citizen that has interacted with the Regional Healthcare Services, to the prescribing physician, and to the facility that has delivered the service;
- an information system that makes information available on the facilities operating at all healthcare levels, the services delivered, the resources used, and the related costs”. (See Report, page 6)

Cabina di regia (at URL:

<http://www.nsis.ministerosalute.it/nsis/paginaMenuNsis.jsp?id=21&menu=organizzazione&lingua=italiano>. See also:

http://www.nsis.ministerosalute.it/imgs/C_22_pagineAree_21_paragrafi_paragrafo_0_listaFile_itemName_3_fileAllegato.pdf)

“In order to coordinate and audit the building phases of the New National Healthcare Information System, a ‘Cabina di Regia’ (Direction Room) has been instituted in 2001, coordinated by the Ministry of Health, and composed of representatives of central government and of Regions. That body also coordinates the implementation of an extensive program activated by Regions and Ministry of Health to develop the semantic interoperability between different regional health information systems and between these and the National Healthcare Information System. Within this program, a specific project (so-called “Patient File”) has two main goals:

- 1) re-engineering some processes (e.g. on registries for patients and healthcare professionals; on the workflow for death certificates);

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2) definition of a framework for EHR development at regional and national levels”. (See Report, page 17)

TSE - Tavolo permanente per la Sanità Elettronica (at URL: <http://www.sanitaelettronica.gov.it/>)

“At the initiative of *Ministry of Innovation and Technologies* and the *Ministry of Health*, a permanent ‘eHealth Board’ (*Tavolo di lavoro permanente per la Sanità Elettronica*) has been active since 2004, as the official setting for discussion and consultation among the Regions and the two proposing ministries, for the harmonization of the e-health policies and for the implementation of the national and regional action plans (including financial planning, as well as actions on education, change management, communication, and the related governance).

The first result of the eHealth Board is the document “Shared policy for eHealth” (*Politica condivisa per la Sanità Elettronica*) which adopts the European Union’s strategic objectives contained in the 2004 e-Health Action Plan, and sets out the main lines of development for accelerating the processes of technological innovation of social and healthcare services, and identifies the intervention settings for defining a regulatory framework of technical rules. (page 7).

In March 2006, TSE published the document “Architectural strategy for e-Health” (*Strategia architetturale per la Sanità Elettronica*, URL: http://www.sanitaelettronica.gov.it/xoops/modules/docmanager/view_file.php?current_file=361¤t_dir=39), whose aim is to outline a reference architectural strategy for the national system of e-Health.

The document constitutes a first high level guideline addressing the design of the national architecture for e-Health (IBSE - Basic Infrastructure for e-Health2), shared within TSE.

The architectural vision has been tackled with by considering some necessary requirements:

- it must guarantee that the clinical information of the patient is available anytime, anywhere;
- it must respect the federated architecture of the Italian Healthcare System;
- it must guarantee a high level of security and be able to respect the Italian legislation on privacy;
- it must have a high level of Reliability/Availability (24x7);
- it must have a modular structure that allows a progressive implementation;
- across the nation, that it is able to cope with obsolescence;
- it must be as less invasive as possible with respect to the existing systems so as to safeguard the already made investments;
- it must use open standards.” (See Report, page 7)

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3.4 Regulatory framework for patients' summaries

Currently, there is no *ad hoc* legislation on patients' summaries in Italy. However, the case falls within the general rules concerning health-related data processing.

Art. 29 Working Party document WP131 of 14 February 2007 on electronic health records (EHRs) has been very influential in Italy, and it is considered also by the national Data Protection Authority as a reference document in the sector of electronic healthcare. Such a document appears to harmonize well with the Italian data protection system.

According to the most recent announcement by the present Italian Government, *ad hoc* legislation on the EHRs is likely to be adopted in the course of the current year, see: <http://www.repubblica.it/2008/06/sezioni/economia/conti-pubblici-71/ricette-online/ricette-online.html>.

The declared aim is to use EHRs in the whole national territory as a means for cost savings in healthcare management.

3.5 Regulatory framework for telemedicine

Telemedicine is not currently regulated through specific legislation, so general rules on data protection and medical liability and ethics apply.

Art. 78, § 5, lett. b) of Decree no. 196/2003 puts a special emphasis on the privacy notice to be given to the data subject in the case of telemedicine, requiring such notice to detail the specific risks of processing health-related data in telemedicine.

It should be added that under art. 37, § 1, lett. b), any processing of health-related data shall be notified to the Italian Authority for data protection, before starting, when such processing is performed via an electronic communication for the purpose of putting in place medical services concerning databases or the provision of goods.

As per art. 163 of Decree no. 196/2003, not accomplishing the above mentioned notification or accomplishing it only in part implies a fine from 10,000 to 60,000 euros and the compulsory publication of the decision in one or more newspapers indicated in the decision itself.

3.6 Regulatory framework for electronic prescriptions

See § 8, which is specific on this issue.

3.7 Overview of relevant legislation

The following is an overview of Italian legislation in the field concerned. Although the applicable legislation is wider than the selection below, it includes some of the most relevant sources.

Sources are ordered in chronological order, starting with the most recent one:

- The code of medical ethics (last version: 16 December 2006) (at URL: portale.fnomceo.it/Jcmsfnomceo/cmsfile/attach_3819.pdf)
- Legislative Decree 24 April 2006, no. 219, implementing Directive 2001/83/EC (consolidated text) on the community code relating to medicinal products for human use and Directive 2003/94/EC (at URL: <http://www.parlamento.it/leggi/deleghe/06219dl.htm>)

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- Law-Decree 30 September 2003, no. 269 (converted into Law 24 November 2003, no. 326) – Urgent norms for national development and for the correction of trends in public expenditures (at URL: <http://www.parlamento.it/parlam/leggi/decreti/03269d.htm>)
 - Legislative Decree 30 June 2003, no. 196 on the protection of personal data (at URL: <http://www.garanteprivacy.it>)
 - Ministry Decree of 19 October 2001, no. 445, concerning the exams for the medical profession certificate (at URL: <http://193.206.110.3/studenti/esamistato/regolamento.htm>)
 - Constitutional Law of 18 October 2001, no. 3, concerning the modification to Title V, Part 2 of Italian Constitution (at URL: <http://www.parlamento.it/parlam/leggi/01003lc.htm>)
 - Decree of the President of the Republic of 9 October 1990, no. 309, titled “Consolidation of laws concerning drugs and psychotropic substances, prevention, cure and rehabilitation from addiction” (at URL: http://www.giustizia.it/cassazione/leggi/dpr309_90.html)
 - Law 23 December 1978, no. 833, establishing the Italian NHS (at URL: <http://www.comune.jesi.an.it/MV/leggi/l833-78.htm>)
 - Law 13 May 1978, no. 180, on voluntary and compulsory medical verifications and treatments (at URL: http://www.ministerosalute.it/imgs/C_17_normativa_888_allegato.pdf)
 - Circolare 178/73¹
 - Decree of the President of Republic 5 April 1950, no. 221 on the professional Registers (at URL: <http://www.med.unibo.it/rad2/Rad/Leggi/221.htm>)
 - legislative Decree of the provisional Head of State 13 September 1946, no. 233 on the rebuilding of the professional Associations in the medical sector and the regulation of the professions themselves (at URL: <http://www.med.unibo.it/rad2/Rad/Leggi/233-1946.htm>)
 - Royal Decree 1706/38, concerning the regulation on the pharmaceutical service. Regulatory framework for the healthcare profession

¹ “Circolare” is an internal administrative source of law, concerning only the application of norms.

4 Regulatory framework for the healthcare profession

4.1 Legal conditions for the practice of healthcare

The legislation in force regulating the healthcare profession is the following:

Decree of the President of Republic 5 April 1950, no. 221 and legislative Decree of the provisional Head of State 13 September 1946, no. 233, on the legal obligation for physicians to hold a University degree in medicine, accomplish a specific training and enrol in specific registers.

Ministry Decree of 19 October 2001, No. 445, modifying the previous Ministry Decree of 9 September 1957. This means that in Italy nobody is allowed to practice medicine, even if limited to diagnosis and prescription of remedies, without holding the necessary legal requirements (University degree, training and enrolment).

Such a rule has been re-stated by the Italian Corte di Cassazione in many decisions: for example, Cass. pen., Sez. VI, 20 June – 6 September 2007, no. 34200; Cass., Sez. VI, 27 March 2003, no. 482; Cass., Sez. VI, 9 February 1995, no. 5838. Even for prescribing homeopathic remedies, it is compulsory to hold the aforementioned legal requirements.

The new legal setting has been in force from 1st January 2004. The duration of the University course in Medicine is 6 years, with a final exam and a written final thesis on a topic of medical interest. After graduation, in order to be allowed to practice in the medical profession, the candidate shall go through a 3-month training and a written exam.

The code of medical ethics is highly valued in the healthcare profession. However, at present ethics in the healthcare sector do not provide for specific obligations concerning eHealth.

4.2 Control over the practice of medicine

As in many other European Countries, the practice of medicine in Italy is supervised by the Order of Physicians. However, unlike most States, in Italy it has not a national basis but rather a local one, which is because of historical reasons. Its official name is “Ordine dei medici chirurghi e odontoiatri”, that is “Order of surgeons and dentists”. All local Orders have a Federation, called the National Federation of Orders of surgeons and dentists.

Basically, both local orders and the national federation are the entities which represent physicians before institutions. They also promote courses, conferences and in general any event which may contribute to enlarging the professional education and skills of its members.

One of the main tasks of the Order is to ensure that rules of conduct and ethical norms, as well as decency and moral standards, are met by its members. In cases of breaches it can issue punishments, ranging from official warnings to being struck off.

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4.3 Professional liability

Professional liability for the medical profession is regulated according to the general rules on liability of professionals set forth by the Civil Code.

The most recent jurisprudence has considered physicians liable also in the cases in which the result has not been achieved.

According to the most recent doctrine and cases, also the organization (ASL (local health units), hospitals, etc.) can be considered liable.

4.4 Professional secrecy

Art. 10 of the Code of medical ethics reads as follows:

“Physicians shall keep secret anything he/she is entrusted with and anything he/she gains knowledge of, during professional medical practice.

The patient’s death shall not exempt physicians from the obligation to secrecy.

Physicians shall inform their fellow workers on the obligation to secrecy. Non-compliance with the obligation to secrecy is a grave misdeed whenever the physician or a third party may draw a profit thereof or whenever the patient or a third party may be damaged thereof.

Not observing the obligation to secrecy is considered admissible on particular reasons, in case it comes from the accomplishment of either a legal obligation (report to the Court, healthcare report, notification of contagious diseases, compulsory certifications) or the obligations set forth in subsequent articles 11 and 12.

Physicians shall not give evidence before a Court on facts or deeds falling within the obligation to secrecy.

Deletion from the professional register shall not exempt physicians from the moral obligation to comply with this present article”².

Professional secrecy is enforced through criminal laws. In particular as per article 622, § 1 of Penal Code, any disclosure of any secret, without a legitimate reason, on the part of he/she who has gained knowledge of it because of his/her personal condition, role, profession, art, or any use by the same person of that secret to his/her or a third party’s profit will be punished, in case it may damage a third party, with a one year prison term or a fine from 30 to 516 euros.

It is also worth mentioning art. 200, § 1 of the Code of Penal Procedure, according to which physicians, pharmacists and anybody practicing medicine are among those who cannot be compelled to give evidence before a Court on what they have gained knowledge of because of their profession, unless they are under obligation to do so.

Legislation on the protection of personal data re-enforces the obligation to secrecy, though in a

² unofficial translation.

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general way, without a specific regulation on the secrecy of the medical profession. As per article 15 of Decree no. 196/2003, whoever causes damage to another person as the result of personal data processing is liable for damages as per art. 2050 of Civil Code. This means that a data controller bears the burden of proof of having taken all proper measures to avoid the damage.

5 5. Processing of personal health-related data

5.1 Short overview of personal data protection legal framework

In Italy a comprehensive legislation on data protection was introduced only in 1996, with Law 31 December 1996, no. 675. However, privacy legislation in specific areas predates such law. Law 675/96 implemented the European Directive 95/46/EC and has been substituted by legislative Decree 30 June 2003, no. 196, which is now the law in force for the protection of personal data, either processed by automatic means or otherwise. Decree 196/2003 also implements European Directive 2002/58/EC and Directive 2006/24/EC.

It must be also mentioned a list of recommendations issued on November 2005 by the Italian Data Protection Authority on the processing of health-related data (at URL: <http://www.garanteprivacy.it/garante/doc.jsp?ID=1191411>). Such document emphasizes the obligation to ensure the respect for the dignity of the patient, to protect his/her privacy, and indicates specific practical rules to be complied with by medical personnel and healthcare providers in various real-life situations.

Generally speaking, Italian data protection law provides a wider and, sometimes, stricter regulation compared to the European directive. In most cases the wording of the European Directives have been literally transposed in the Italian text, while in other cases Italian legislator has allowed itself a certain degree of discretionary in the implementation process. Among the most notable differences from the EU text, there are the following:

- data subjects can also be legal persons and not only natural persons;
- communication and diffusion of personal data have been singled out as specific cases of processing, sometimes regulated with dedicated rules;
- introduction of the principle of necessity, after the German legislation on data protection; and, most notably,
- the requirement of consent of the data subject for medical treatment, even when it is supplied by a public health institute.

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

Under art. 8, § 3 of Directive 95/46/EC, health-related data can be processed without data subject's consent "where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy". While Belgium, France, Germany, UK and most European Countries has stuck to this rule, Italy has chosen a stricter regime, posing data subject's

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consent as a necessary requirement even in case of medical diagnosis, provision of care or treatment or management of health-care services, etc.

Art. 76, § 1 reads: “1. Even when performing an activity of relevant public interest, as for article 85, health professionals and public healthcare entities can process health-related personal data:

a) with the data subject’s consent, and without the authorization of the Italian Data Protection Authority, if the processing concerns data and operations that are necessary for the sake of the data subject’s health and physical condition;

b) without the data subject’s consent, but with the necessary prior authorization by the Italian Data Protection Authority, if the purposes referred to under a) concern either a third party or the community as a whole”.

As concerning the processing of personal health-related data for administrative reasons, art. 85 (Tasks of the National Health Service) reads as follows: “1. Except for the cases referred to in paragraph 2, such purposes shall be considered of substantial public interest –as per articles 20 and 21– which fall within the tasks of the National Health Service or of other public healthcare entities if they concern:

a) administrative activities related to prevention, diagnosis, cure and rehabilitation of National Health Service clients, including medical assistance provided to non-Italians, Italians living abroad, seamen and airport staff;

b) planning, management, control and assessment of healthcare assistance;

c) monitoring of medical experimentation and drug prescriptions, authorization to sell and import medical drugs and other health-related products;

d) certification activities;

e) application of legislation on hygiene and safety in working places and legislation on health and safety of population;

f) administrative activities related to organ and tissue transplantations and human blood transfusions, also pursuant to Act no. 107 of 4 May 1990;

g) setting up, managing, planning and monitoring the relationships between the administration and the entities bound by contractual agreements with and/or recognised by the National Health Service.

2. Paragraph 1 shall not apply to the processing of health-related data carried out either by healthcare professionals or by public health care entities for the purpose of protecting the health or physical condition of the data subject, or of a third party or the community as a whole, in which case the provisions concerning the data subject’s consent and/or Italian Data Protection Authority authorization shall apply as per art. 76.

3. (...)

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4. (...)”.

In an important communication on 28 October 2003 (see URL: <http://www.garanteprivacy.it/garante/doc.jsp?ID=425284>), the Italian Data Protection Authority held that databases in the healthcare sector shall process only anonymous data. Such decision has been issued concerning Decree 30 September, no. 269, which envisaged the establishment of a database containing a unique identifier (“codice fiscale”) capable of linking medical products with a specific person.

5.3 Information and access rights of data subjects

Art. 7 of the Italian data protection law deals with the right of the data subject to access his/her personal data, but does not provide specific rules for health-related data.

However, this general setting must be considered in connection with art. 84, § 1, applying only to data processing in the healthcare sector. Hence, according to art. 84, § 1, data subjects can be communicated their health-related data only through a physician selected either by the data subjects themselves or by the processor. The ground for such a norm is clear: to avoid unnecessary shocks to data subjects, because, generally speaking, it takes a physician to adequately explain the significance of medical information to data subjects.

It is worth mentioning art. 60 of Decree no. 196/2003, concerning health-related data processing performed by public entities. According to that norm, third parties can access such data only if the right they waive is at least equal in rank to the data subject’s rights, or else if it consists in a personal right or another fundamental, inviolable right or freedom.

5.4 Other aspects of Italian regulation

A common rule either for public and private entities is the prohibition on disseminating health-related data: see articles 20, § 8 and 26, § 5.

Special security measures shall be taken when processing health-related data. Under article 34, §, lett. h) processors who operates in the healthcare sector shall implement encryption techniques or identification codes for specific processing operations when dealing with health-related data and data on sexual life.

As per art. 24 of Attachment B to Decree 196/03, healthcare professionals and healthcare entities shall separate health-related data from other data subject’s personal data.

As in many European Countries, in Italy sensitive data in general and health-related data in particular can be freely used for statistical purposes, provided they have been anonymised; that is, disconnected from data subjects’ identifiers.

In Italy patients can freely choose GPs, and of course change them.

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Health professionals have the duty, which is either legal and deontological, to provide patients with all relevant information necessary to assess their diagnosis and cure. Communication with the patient must take place in clear language, adapted to individual needs.

5.5 Genetic data

Italy has issued a special regulation for what concerns genetic data, which are a sub-category of health-related data. Genetic data are expressly mentioned at article 90 of Decree 196/2003 and art. 24 of Attachment B to the aforementioned Decree.

Further, a recent new regulation has been approved on 22 February 2007 by the Italian Data Protection Authority, establishing a comprehensive legal framework for the secure processing of such data.

6 Rights and duties of healthcare providers and patients

The general principles on which Italian healthcare system is built on are stated in the mentioned law no. 833/78, establishing the National Health Service. Other basic rules can be found in other sources of law. Others are embodied in the Code of Medical Ethics.

For further reference material see “Libro bianco sui principi fondamentali del servizio sanitario nazionale”, 2008, by Libera Università di studi sociali - Luiss “Guido Carli”, *Centro di ricerca sulle amministrazioni pubbliche “V. Bachelet”*, available online at URL http://www.ministerosalute.it/imgs/C_17_pubblicazioni_808_allegato.pdf.

6.1 Basic principles

The most basic principles are the right to freely choose the physician, the right to freely choose the place of cure, the right to be informed and the right of consent.

6.2 Right to free choice

Anyone enjoys the right to freely choose the so-called “medico di base”, that is the GP or the paediatrician. However, such freedom of choice could be limited by the fact that physicians cannot have patients beyond a maximum number.

The choice of the physician expires after one year but it is subject to a tacit renewal.

The right of free choice encompasses the right to change one’s mind and change physician. Physicians and paediatricians on the other hand cannot refuse their selection made by patients, except for exceptional reasons.

See art. 8 of legislative Decree 30 December 1992, no. 502, and subsequent modifications.

6.3 Right to choose the place in which the healthcare is provided

Closely linked to the right to free choice of a physician is the right to choose the place in which the healthcare is provided. According to article 8-*ter* of legislative Decree no. 502/1992 and article 2, § 1, letter *d*) of law no. 419/1998, such freedom of choice shall be enjoyed within the framework of the healthcare programmes. Similarly with a GP or paediatrician, there is a maximum limit set for any healthcare provider.

6.4 Rights to information

For some basic norms see above § 5.3 and following § 5.4.

6.5 Right to complain

According to art. 14, § 6, of legislative Decree 30 December 1992, no. 502, any patient, his/her relatives, persons related by affinity and entities for the protection of rights can address healthcare providers' reports and complaints, at no expenses, within the deadline of fifteen days from whatever originated the report or the complaint.

The director of the healthcare provider shall decide within fifteen days. Any recourse to this

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instrument does not prevent going before a Court.

6.6 Some rights embodied in the code of medical ethics

The code of medical ethics (last version: 16 December 2006) is more explicit as to information and consent, which are regulated in articles 33 and 35 respectively.

Art. 33 reads as follows:

“Physicians shall provide their patients with the most appropriate information on either their diagnosis and prognosis, on the perspectives thereof, the possible alternatives in terms of diagnosis and prognosis and the likely consequences of the choices being made.

In giving such information, physicians shall evaluate patients’ capacity to understand, in order to promote the most comprehensive acceptance of the above diagnostic-therapeutic proposals.

All further requests for information from the patients shall be satisfied.

Physicians shall also meet citizens’ information requests in matter of prevention.

Information concerning serious or grave prognoses or those which may cause worry suffering to the patients shall be given carefully, using non-traumatic terms and not excluding elements of hope.

If patients choose not to be informed or nominate any other person or persons to be informed on their behalf, the choice of such patients shall be respected”³.

Art. 35 reads as follows:

“Physicians shall not begin any diagnostic and/or therapeutic activity without the prior informed consent of the patient.

Consent shall be expressed in writing in those cases which are provided by law and in those in which either the specific diagnostic and/or therapeutic activities or the possible consequences to the patient make it appropriate that the latter expresses his/her will. Such a consent adds to and does not substitute for the information as per art. 32.

Diagnostic and/or therapeutic treatments that may determine a serious risk for patients shall be initiated only in case of extreme necessity and prior information to patients on the possible consequences. The following consent shall be appropriately documented.

In any case, in the presence of a documented refusal of any patient in full possession of their faculties, the physician shall not undertake any diagnoses or cures, no medical treatment against the will of the patient being allowed.

Physicians shall provide medical assistance to incapable people with all due competence and understanding respecting human dignity and the quality of life, avoiding any unnecessary treatment and taking into account the patient’s previous will”⁴.

³ Unofficial translation.

⁴ Unofficial translation.

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Disregarding the medical code of ethics bears legal consequences for physicians.

As already mentioned, such informed consent to medical treatment is not the same as the data subject's consent for data processing (though the latter has been framed in similar terms). As a result, patients have to give at least two separate consents: one for medical treatments or diagnoses and one for the necessary health-related data processing that all this involves.

6.7 Consent**6.7.1 The constitutional framework**

The major legal source for patient's free consent to medical treatment is to be found in Constitution, namely in articles 2, 13 and 32. Art. 2 guarantees the fundamental right of any human being, among which is the right to self-determination. Art. 13 concerns the personal freedom, involving also the liberty to dispose of his/her own body, as recognized by the Italian Constitutional Court with the decision of 22 October 1990, no. 471. Art. 32 recognizes the right to health as a fundamental right for the individual and as in the interests of society, and grants healthcare for the disadvantaged. Most importantly, it says that nobody shall be obliged to undergo any medical treatment unless provided by law. However, the law itself cannot, in any circumstance, cross the boundaries of human respect.

6.7.2 Laws

The most notable legal sources here are art. 1 of Law 13 May 1978, no. 180, on voluntary and compulsory medical verifications and treatments and art. 33 of Law 23 December 1978, no. 833, establishing the Italian NHS. In particular, according to the latter one, medical verifications and treatments shall, as a rule, be on a voluntary basis. Even in the case of compulsory medical verifications and treatments, as per the wording of art. 32 of Constitution, the right to the free choice of a physician and any healthcare structure shall be guaranteed as far as possible.

Compulsory healthcare visits and treatment can be decided by city mayors in their role of local health authorities, based on the opinion of a physician.

The norm also stresses the fact that initiatives shall be taken in order to grant consent to and participation of those who are subject to the aforementioned compulsory verifications and treatments.

7 Identity management in the healthcare sector

7.1 Patients' identification

Tessera sanitaria. Art. 50 of Legislative Decree 30 September 2003, no. 269 (converted by Law 326/2003) introduced a new instrument to the Italian healthcare system, the “tessera sanitaria” (healthcare card). It is a personal card with a magnetic strip and identifies all Italian citizens and those residents having access to the NHS with a personal code. Such an instrument, valid throughout the EU, is also a means for monitoring expenses in the healthcare sector.

Carta nazionale dei servizi. Some Italian Regions have issued smart cards to allow their citizens a direct access to healthcare services. Such cards replicate the format of “carta nazionale dei servizi” (national card of services), which is basically a card with a microchip containing an advanced electronic signature and a certificate, which is allotted to citizens in order to make them use online services issued by Public Administrations.

A working example of such cards to be used in the healthcare sector is the CRS-SISS card of Region Lombardia, which we will deal with below.

7.2 The CRS-SISS Project

The CRS-SISS Project (<http://www.crs.lombardia.it/>) is not only a system for creating and managing patients' EHRs, but it also implements a system for patient identity management based on a smart card with a PKI architecture.

Generally speaking, CRS-SISS Project allows general practitioners and physicians, public and private hospitals, health care providers, chemist's and the Region Lombardia to inter-connect with each other for a variety of purposes, ranging from the management of health expenses (Region Lombardia) to the online reservation used in hospitals and other structures, to the communication of patients' health-related data. Of course the basic goal of CRS-SISS Project is to accomplish electronically and in an effective time-saving manner some of the most common activities in the healthcare field.

It must be stressed that fluxes of data follow specific and differenced channels, depending on the role and the legal status of the subjects involved in the communication of data. For instance, Region Lombardia is allowed to access only administrative data and has no access to sensitive data; physicians are allowed to see their patients' data, provided such patients have given them express consent.

Project CRS-SISS is fully compliant with CNIPA (Italian National IT Center for the Public Sector) standards and therefore fully interoperable at a national level.

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The core of the CRS-SISS Project is a 'Healthcare Extranet', which links operators, social services, organizations and citizens, tracking all the events which occur in the medical care and providing value-added services.

Through the mentioned PKI-based smart card (technically the CRS card) both citizens and physicians are able to access the network.

The level of security is high: an advanced electronic signature is used for identifying patients and securing their data; all communications within the network are encrypted; and health-related data are not stored in a unique central archive: rather they are disseminated in all the hospitals which process them and temporarily collected together for a quick consultation.

In brief the main features of CRS-SISS Project are:

- ✓ patients identification
- ✓ EHRs
- ✓ electronic prescription and provision of healthcare services
- ✓ support to GPs' patients dossiers
- ✓ online results of medical exams
- ✓ online booking in hospitals and other healthcare providers
- ✓ emergency data management
- ✓ management of accounting information flows
- ✓ secure exchange of health-related information among physicians

At present citizens with access to CRS-SISS are around 9.000.000, which means almost 99% of the entire population of Region Lombardia. Almost 50 big healthcare providers, both public and private, are involved.

In the previous years CRS-SISS Project has allowed GPs to issue something like 3 million prescriptions per month, i.e. 50% of the whole Lombardia.

7.3 Project SOLE

Project SOLE (<http://www.progetto-sole.it/consultazione/home.php>), established in Region Emilia-Romagna, allows GPs to directly communicate patients' medical data to public hospitals through secure channels. Among other features, such software is capable of directly communicating with applications running on the user computer. The goal of project SOLE is to electronically perform some of the most time-consuming and most common operations in the field of public health, like for instance delivering a medical prescription to a hospital, making a reservation or receiving a medical report.

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In brief, SOLE has been developed as a means of meeting: the emerging necessity for citizens to feel connected to the world of healthcare; the need of general practitioners, family paediatricians and hospital physicians to have a secure channel dedicated to the exchange of information; and finally the need of healthcare companies to formalise and speed up procedures.

As for the advanced electronic signature, it must be acknowledged that such an instrument has not yet been implemented comprehensively, covering only some areas. However the implementation of the advanced electronic signature in the project is expected in the short term. When such stage is accomplished the project will be fully compliant with Italian standards for Public Administration and completely interoperable at a national level. The card used for advanced electronic signature will be of the “Carta Nazionale dei Servizi” type, which means an instrument very similar to the above mentioned CRS-SISS card.

The advantages of the prescription/referral life cycle management structure of the project are the following:

- timely knowledge about visit results and verifications by GPs/family paediatricians;
- uploading data online by whoever acquires the prescription;
- reducing patient transfers;
- slimming down administrative procedures to manage compensation for medical travel expenses.

The advantages of the management structure of the project are the following:

- reduction of red tape for GPs/family paediatricians as well as for citizens so as to ease the definition and management of diagnostic treatments;
- improvement of the communication processes between GPs/family paediatricians, other local entities and hospital medical specialists;
- “real time” availability of sanitary information (services, prescriptions, referrals, clinical data, hospitalization) in an electronic format;
- standardisation of codes at a regional level.

It guarantees a timely and comprehensive communication between the GPs/family paediatricians and hospital professionals from the beginning to the end of the hospitalization.

7.4 IESS Programme

IESS Programme (see http://iess.regione.veneto.it/portal/page?_pageid=1,52378&_dad=portal&_schema=PORTAL) stands for “Integrazione per l’Erogazione di Servizi in Sanità”, that is “Integration for Health Services delivery”

Quoting from Mercurio, Rossi Mori et al., “eHealth strategy and implementation activities in Italy”, p. 18, the objectives of IESS are the following:

“ • Allowing direct approach of citizen to medical facilities (as well as services, booking offices, GP

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practices, chemists, emergency) by telematic tools;

- set up of Electronic Health Record (FSP: Fascicolo Sanitario Personale) with electronic data about services received by patients, to which both medical staff and patients can gain access, in order to guarantee the continuity of treatment process;
- set up of 105.000 smart card for the authentication on line for the citizen of two Health Local Unit in Bassano del Grappa e Mirano/Dolo;
- set up of 200 professional card for the digital sign for the medical staff of the 2 Local Units;
- set up of a interoperability network system, based on the “domain gate” and "egov envelope", for all the health local unit of the region for the electronic booking and the EHR;
- Agreement with the Ministry for Innovation and Technologies for development and test of an interoperable and cooperative prototype named IBSE (Infrastruttura di Base per la Sanità Elettronica – Basic infrastructure for eHealth)”.

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8 Regulatory framework for electronic prescriptions

Generally speaking, all prescriptions shall be written, dated and signed by a physician. When sending the prescription, the pharmacy shall stamp, date and sign it, indicating the cost. Such requirements result from the following legal sources: Royal Decree 1706/38, concerning the regulation on the pharmaceutical service, Circolare 178/73, Legislative Decree 24 April 2006, no. 219.

As per art. 89, § 3 of the latter, prescriptions that have to be renewed from time to time, due to the characteristics of the medicinal products, shall expire after 30 days. Such prescriptions shall be given to the pharmacist, who shall keep them for 6 months, unless he/she hand them over to the competent authority for receiving the NHS refund. After expiration of that period, the pharmacist shall destroy the prescriptions in such a manner as to make sure third parties cannot access the data therein indicated.

Under § 4, the physician shall specify the “codice fiscale” of the patient. That is a unique identifier attributed by the Italian Income Agency.

Under § 5, prescriptions shall clearly indicate, either in printing or as a stamp, the prescribing physician and the pharmacy in which he/she works. It shall also bear the date and the signature of the physician, as well as any relevant information about NHS exemptions.

It must be noted that as per art. 87 of legislative Decree no. 196/2003, prescriptions for treatments which are, even in part, at the expenses of the NHS shall meet certain privacy requirements. For instance, they shall be made in such a manner to allow the identification of the data subject only in case of necessity.

There is not a specific legislation about electronic prescriptions in Italy. However, they easily fall within the existing norms. As a matter of fact, electronic prescriptions have already been in use for some time. The above mentioned CRS-SISS is a clear example of implementation of electronic prescriptions.

Prescriptions shall be in writing, bear a date and be signed by a physician.

These conditions are met by the legislation on “firma digitale”. Such a system allows an electronic document to be time-stamped. In Italian legislation “firma digitale” and handwritten signature have the same legal value. Such rule is set forth by Presidential Decree no. 82/2005, entered into force on January the 1st, 2006.

In Italian legal framework, there are basically two levels of electronic signatures:

- “firma elettronica”, corresponding to the electronic signature; and
- “firma elettronica qualificata” corresponding to electronic signature with a qualified certificate and created by a secure-signature-creation device. Currently, the only existing example of “firma elettronica qualificata” is the already mentioned “firma digitale”, which is based on a PKI infrastructure and is created using a smart card or a token.

These two levels of electronic signatures have different legal implications.

Electronic documents signed with electronic signatures. Pursuant to art. 20, § 1-bis of Legislative Decree no. 82/2005, it is up the judge to evaluate whether or not an electronic document, whether or not signed with an electronic signature, could be considered as a written document. The judge shall take into account its

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objective characteristics of quality, security, integrity, inalterability.

However, if it is subscribed using a “firma elettronica qualificata”, it shall be considered as in writing (see art. 20. § 2).

Electronic signatures as evidences. As per art. 21, § 1 of Legislative Decree no. 82/2005, an electronic document subscribed with an electronic signature can be freely evaluated by the judge, taking into account its objective characteristics, like quality and security.

Art. 2712 of Italian Civil Code reads as follows:

“Photographic, electronic or cinematographic reproductions, phonographic recordings, and in general any other mechanical representation of facts and things make conclusive evidence of facts and things represented therein, if the person against whom they are offered does not dispute their conformity to the said facts and things”.

That provision was also applicable to electronic documents under previous legislation. The Italian Supreme Court (Corte di Cassazione) has decided that an electronic document, without any signature, can be used as evidence in a trial⁵. Tribunals, under previous legislation, have issued decisions in which an email has been considered as possessing enough requirements as a written evidence in order to obtain a decreto ingiuntivo (type of judicial order)⁶.

Finally, as per art. 21, § 2 of the above mentioned Decree, electronic documents subscribed with “firma digitale” have the same value as evidences as written documents recognised by the party who wrote them, which means a conclusive evidence, until objection, of the origin of the declarations from the person whom has signed it (see art. 2702 of Italian Civil Code). It is important to stress that the legal holder of the signature device is considered to be the subscriber, unless he/she proves the contrary.

⁵ Cf. Cass. 11445/2001 and Cass. 9884/2005.

⁶ Cf., among others, Trib. Cuneo 15.12.2003, Trib. Bari 20.1.2004, Trib. Lucca 17.7.2004.

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9 General assessment

In Italy a comprehensive *ad hoc* legislation on eHealth at a national level has not been already issued. However, the regulation on digitalization in the public sector and the norms on the electronic processing of health-related data encompass many topics concerning the eHealth domain.

It should be added that starting from 2001, some State and State-Region bodies have been attributed the task of studying programmes and interventions in the fields of eHealth.

The absence of specific legislation only concerns certain applications and distinctive areas in the eHealth sectors, as, for what concerns general principles, it can be fairly assumed that they are long established.

In order to completely understand the Italian framework concerning eHealth, one has to bear into one's mind that, following the Constitutional reform of 2001, the management of the healthcare system falls within the competences of the Regions, which means that also the electronic transposition of healthcare services is up to the Regions. The State maintains the power to determine the general principles and to establish the essential levels of assistance.

Some regional applications of e-Health systems are currently working in Italy. To mention three of the most developed: CRS-SISS, SOLE and IESS.

EHRs, telemedicine and e-prescriptions are not currently covered by to-the-point legislation. However, notwithstanding the fact that legislation in force does not cover specifically all the areas falling within the notion of eHealth, the system does not appear to be incomplete, provided that norms with a broader spectrum and general principles cover also such topics that are otherwise not expressly regulated, in manner to be considered appropriate.

Where efforts would really be welcomed is more likely the applicative and practical side of this framework: such as harmonization of procedures, indication of standard conducts, and a co-ordinate approach in the organization process.