SMART 2007/0059

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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE FRANCE

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European Commission
Directorate General Information Society

Brussels

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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
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[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.

2.2 Acronyms

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 French healthcare system

A comprehensive overview of French healthcare system (2004) can be found in the French Hit country report published by the European Observatory on Health System and Policy (written by Simone Sandier, Valérie Paris and Dominique Polton).
http://www.euro.who.int/document/e83126.pdf (156 p.)
From this report, we reproduce some important observations (the following paragraphs are extracted from the report except for the first one which has been adapted to recent changes in the legislation).
The organisation of the French healthcare system relies on a sharing of competences between the State, the Health Insurance (Assurance Maladie) and the local authorities. The State bases its health policy on objectives set up for 5 years in a Law voted by the Parliament. To that effect, it relies on a series of agencies: the High Level Council on Public Health (*Haut conseil de Santé Publique*) provides guidance and assists in decision-making regarding public health problems and issues related to the organization of health care. The National Health Conference (*Conférence Nationale de Santé*) put together the health systems stakeholders, and proposes priorities and orientations for health policy. The National Institute for prevention and education (*Institut national de prevention et d'éducation pour la santé* – INPS) is in charge of implementing the health programmes managed by the State. Regional Health Conferences (*Conférences régionales de Santé*) bring together regional stakeholders, institutions, healthcare providers and patients. They analyse the local health needs and establish public health priorities at their level. Local authorities mainly intervene in three domains: prevention measures for the youth (preschool, elementary education), care of the elderly and formation of non-medical healthcare providers.[1] The territorial organisation is extremely complicated by the intervention of numerous actors.
"Financial responsibility for health care in France is mainly borne by the statutory health insurance system as a branch of the wider system of social security. Since 1 January 2000, statutory health insurance covers the whole population, although it only funds three quarters of health spending, so there is considerable scope for complementary sources of funding. The rules for reimbursement are based on several general principles: the health insurance system grants people access to the registered health care professional of their choice; in general, there is no limit to the volume of goods and services reimbursed; doctors have considerable freedom in prescribing, although they must comply with practice guidelines."
"Although the general rule is that reimbursement by statutory health insurance only takes place after direct payment has been made by the patient to the provider of the good or service, there are situations in which the patient is exempt from making the initial direct payment. There is usually a discrepancy between the actual amount paid by patients and the amount

[1] L'organisation du système de santé publique, *Santé publique* 2004/4, N° 44, p. 645-654; and Ritter P., Rapport sur la creation des agences régionales de santé présenté au Ministre de la Santé, de la Jeunesse et des Sports, Janvier 2008.

they are reimbursed by their health insurance fund. This discrepancy is either borne by patients or by the complementary VHI (voluntary health insurance) scheme to which they subscribe on a (usually) voluntary basis. Complementary VHI coverage is provided by three types of organization: mutual insurance associations; private for-profit insurance companies; provident institutions."

"Methods of paying health care professionals vary according to whether the professionals concerned are self-employed (that is, independent professionals engaged in private practice) or employed by institutions. However, it is common for professionals to have mixed activities, so their total remuneration is likely to be a composite sum. In most cases, self-employed professionals are paid directly by patients at the time of the provision of the service; the statutory health insurance system usually only reimburses the patient at a later stage, and usually only partially. Health professionals are not free to fix the rates they charge for their services and are required to apply the official charges set out in the agreements. However, there are notable exceptions, particularly for doctors holding a permanent right to exceed the official charges and those who have opted for a so-called second sector with variable fees. Doctors working in public hospitals are state employees who benefit from conditions of employment similar to those of civil servants."

"Hospitals in France can be public, private non-profit or private for-profit. They can be specialized or non-specialized. The system for paying public hospitals is essentially prospective. The remuneration of for-profit hospitals has two components: on one hand, fixed-rate payments covering the costs of accommodation, nursing and routine care, drugs and minor supplies; on the other hand, a payment based on the technical environment that is directly linked to the nature and scale of the diagnostic and therapeutic procedures carried out. Doctors providing treatment in private for-profit hospitals are paid on a fee-for-service basis. Private non-profit hospitals may or may not participate in the public hospital service. If they are, they are paid as public hospitals; if they are not, they can choose between the two systems of payment (public hospitals or private for profit hospitals)."

"In order to qualify for reimbursement by the statutory health insurance system, a drug must be included in the positive list of reimbursable drugs established by ministerial ordinance on the advice of the Commission on Transparency and the Economic Committee for Medical Products (CEPS) Pharmacies have a monopoly on the dispensing of medicines. Only qualified pharmacists can be proprietors of a retail dispensing pharmacy or form a company to run a retail pharmacy. These pharmacists or companies cannot be proprietors of more than one pharmacy. There were about 22 700 retail pharmacies in 2000. Unless special dispensation is granted, the establishment of pharmacies is regulated by a numerus clausus that takes into account both the size of the population to be served and the distance involved in getting to the nearest pharmacy."

3.2 Use of ICT in the French healthcare sector

There are no recent and reliable data on the use of ICT by French specialists, hospitals or pharmacies. A recent (2007) status of the use of ICT by *general practitioners* in France has

been drafted in the framework of the European Pilot Study on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe" (Empirica): http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
From the French country brief, we take over the following key findings:
"In terms of infrastructure, 83% of the French GP practices use a computer. 73% of practices dispose of an Internet connection. In France, broadband connections are not yet universal; they are however already available in nearly 60% of GP practices.
When it comes to the use of eHealth solutions, France shows results that are more or less in line with EU27 averages. This holds true for example for the use of computers in consultation with the patients which is taken advantage of by 72% of French GP practices as compared to a EU27 average of 66%. With regard to local the storage of electronic medical patient data France scores slightly above the EU27 average as well. Especially remarkable is the high share of stored radiological data which in France is stored two times the average.(65% versus 34%). Decision Support Systems are used to a slightly lesser extent than in other countries of the EU.
The use of electronic networks for the transmission of medical patient data is not yet well established in France. Only 5% of the GP practices participating in the survey reported having exchanged medical data with other care providers via some sort of network, 33% having received analytic lab results this way. The shares might increase in the upcoming years due to an Internet based electronic health record (Dossier Médical Personnel - DMP) already under way.
ePrescribing has not really arrived on the agenda of European GPs it is practiced by only 2% of French GP practices and 6% on average in the EU27. The exchange of administrative data with reimbursers on the contrary is well developed in France: 85% of GP practices report the use (as compared to 15% on average in the EU27)."

3.3 National eHealth strategy

An overview of the French eHealth policy can be found in the March 2007 ERA Fact Sheet "eHealth strategy and implementation activities in France": http://www.ehealth-era.org/database/documents/factsheets/France.pdf
For our Study, the following observations, extracted from this fact sheet, are important:
"In France, during the past decade, the importance of Health Information Systems and eHealth has been expressed in a series of laws in the field of public health and social security. Under the responsibility of the Minister of Health, the development of eHealth initiatives continues to be a major objective for the French government.
Recent official reports concerning aspects of eHealth development in France include:
• A report by the Parliamentary Office for the Evaluation of Scientific and Technologic Choices (OPECST), entitled "New Information Technologies and Healthcare Systems" (June 2004); a report by the General Council of Information technologies issued by R. PICARD et B. SALGUES in 2007 entitled "New Information Technologies and Health; Which policy?" (2007); a report on by M. GAGNEUX entitled "For a shared virtual patient file and a national strategy of health information systems" commissioned by the Ministry of Health (2008). On

the specific issue of the personal medical file, a report commissioned by the Parliament to J.-P. DOOR (2008).
• A report by Bérengère Poletti, Member of the Parliament (projet de loi de financement de la sécurité sociale, 2005).
• Reports, mainly focused on the governance issues, from the"Cour des Comptes" and the "Inspection Générale des Affaires Sociales" (IGAS). Both reports "Gagneux" and "Door" deal with the issue of governance of ehealth systems.
The recommendations of the OPECST report which focused mainly on hospitals include, among others: an outline of eHealth funding for hospitals; creation of a specialisation in eHealth and associated specific training by medical faculties; primary care providers charged with public duties should have online links to a hospital; potential creation of a regional eHealth coordination structure under the responsibility of the director of the Regional Agency for Hospitalisation, on behalf of the Ministry of Health, in partnership with local elected authorities; and generalised eHealth in all penitentiary settings. The new global plan for the hospital sector was recently announced by the Minister of Health under the "Hospital 2012" plan (155 projects were accepted by the government for hospital system of information).
Four major objectives have been outlined for eHealth in France:
• Contribute to national public health objectives: improve organisation and coordination of care.
• Contribute to national planning objectives: facilitate the access to proximity healthcare, in particular in rural areas.
• Contribute to the training of healthcare professionals.
• Ameliorate the problems arising from demographic change (for citizens, patients and health care professionals).
The national strategy is mostly targeted at the optimisation and reengineering of the healthcare system. The underlying global objectives are to achieve improvements in the quality and the continuity of care for each citizen. On this basis financial resources have been devoted to the development of eHealth through a diverse range of national plans, among which the most recent include Périn@t (perinatal plan), e-s@nte 2000, 2001, 2002, FMESPP (Fund for the Modernisation of Public and Private Hospitals), CPER (State-Region Planning Contracts), CIADT (Inter-ministerial Committee for Territory Planning) and FAQSV (Fund for Primary Care Quality Improvement).
Legislation exists in the area of data protection, telemedicine, eHealth service provision and Health-IT product liability, as well as Electronic Health Record. The legislation of 1996, 2000, 2002, 2004, 2006 and 2007 concerning the Public Health and the Social Security sector is of particular relevance."
"eHealth has been implemented at both local and regional levels. A national eHealth virtual community has also been realized through the national mapping of all eHealth initiatives.
Relevant well-known practical eHealth implementations include:
• The CPS (Carte de Professionnel de Santé – Health Professional Card) is a microprocessor card managed by the GIP CPS, a dedicated structure created in 1993, and reinforced on the basis of the Juppé's 1996 law. The CPS functionalities include identification, authentication

and electronic signature of health professionals and its use is mandatory for the storage and exchange of medical data.
• The SESAM-Vitale system uses a microprocessor card (carte Vitale) which contains health insurance data for the insured and their beneficiaries. It replaces paper forms by electronic reimbursement claims (Feuilles de Soins Électroniques, FSE) controlled by the simultaneous usage of the health professional and insured person's cards. In the near future, the Vitale card will be replaced by a new one, the Vitale 2.
• EU NETC@RDS Project, coordinated by SESAMVitale Economic Interest Grouping, aims at improving the access of mobile citizens to trans-European health services through a cross-insurance fund (contractual financial) verification of the personal social insurance rights and acceptance of the costs incurred for the healthcare provided.
• The official Health Web Portal in France has been developed under the auspices of the Health General Directorate of the Ministry and aims at promoting information from public agencies working on public health topics. Other important health portals were launched, such as the Plan Cancer, which is the public information website of the national health priority on cancer prevention, as well as dedicated information and recommendations about the quality of the health web sites and services. The Act of 30 January 2007 (article 25) organizes one mutual portal for the personal medical records (DMP) and pharmaceutical records (DP),
• The Mandatory Insurance Organizations are continuing to develop. 38 dedicated applications for the Healthcare professionals, for example an application which allows medical doctors to securely access information about the previously reimbursed actions or prescribed drugs concerning their patients.
• Several outstanding regional applications and platforms, in the fields of telematics, telehealth, and telemedicine are already in use in different regions, as well as specialized dossiers like the DCC (Dossier Communiquant Cancer). The DMP project (Dossier Médical Personnel - personal medical record), one of the most important aspects of the 2004 law, is now presenting a real opportunity to organize the liaison and the articulation at the national level between the local regional projects and the national one, by building on accepted "reference practices" for security and interoperability based on international standards, for the benefit of the patient. This Act provides for the right of every patient to have a DMP, hosted by an accredited personal data host provider, which would include all diagnostic and therapeutic information and allow for the coordination of cares provided to the patient. The act does not however define the content of such files but let the task to a future decree. This decree is being drafted and so far foresees the introduction of the following information: identification of the owner, general medical data (medical and surgery history, summaries and medical certificates), cares, prevention, medical imagery, expression of the owner. The GIP-DMP, in charge of the conception and implementation of the DMP, is coordinating with healthcare professional and patient organizations the definition of the summaries to be included.

Pursuing the development of eHealth initiatives is a major objective of the French government. The eHealth developments envisioned over the next few years include:

• Further development in the use of current eHealth applications, and the emergence of more new applications consistent with the eHealth information system strategic global plan.
• The adoption of validated standards for the implementation of eHealth projects.
• Agreement on the definition of clinical, economic and organizational evaluation criteria.
• The design and implementation of financing schemes and new economic models.
• A better awareness and acceptance of best practices.
The Mission pour l'Informatisation du Système de Santé (MISS), the eHealth department directly linked to the general secretary of social ministries, was recently asked by the minister to elaborate a global strategic plan on eHealth and health information system. It has already launched a wide consultation with all the concerned stakeholders. Seven working parties have been created."

3.4 Regulatory framework for patients' summaries

France doesn't have legal provisions in the area of patients' summaries. As mentioned above, the drafted decree on the content of the DMP includes patient summaries. The content of the summary is however still under discussion.
Provisions are foreseen for the creation of an electronic health records for the follow-up of children' health condition (*carnet de santé*). Children's' health records contain the results of the mandatory preventive examinations that base the issuance of a health certificate. Regulation is pending in order to define the articulation between the DMP and children' health records.
{On the other hand, private initiatives have tended to develop electronic health records. "Monpass.santé" is a smart card with a secured chip (cleyris TM), PKI based and a PIN code that has been developed by Orange Business Services together with the Mutuelle Générale (a private healthcare insurer). The card can be read with physicians' Vital Card readers. It contains a vaccination's history of the patient. The patient can access a personal area on the website of the healthcare insurance, consult his vaccination agenda and the ones of his beneficiary and receives alerts related to vaccination obligations.[2]]

3.5 Regulatory framework for telemedicine

The Healthcare Insurance Act (13 August 2004) provides a legal basis for the practice of telemedicine. Article 32 defines telemedicine as the practice of medical acts on distance, under the control and responsibility of a physician, in direct contact with the patient, through communication means appropriate to the performance of the act. It moreover subjects the practice of telemedicine to the strict compliance with professional ethics rules.
Two uncertainties arise from this definition, namely what should be understood by the expression "in direct contact with the patient" and whether this article refers to a clinical and

[2] Press release, Monpass.santé: premier carnet de santé électronique, available online at: http://www.imedicale.fr/document/1593

physical relation between the physician and the patient or a virtual relation with no clinical examination.[3]
To answer these questions, the National Council of the Order of Physicians has analyzed the ethics rules applying to telemedicine and has defined six criteria to guide its practice:

- Only the health condition of the patient could justify the use of telemedicine in specific circumstances (emergency, insufficient number of physicians in a defined area, etc.).
- The technical and communication means, the competence and qualification of "tele-experts" should meet quality requirements, independently of the problems that could stem from health economics.
- The patient should freely consent to the use of telemedicine. The information should be simple, concise and accurate. Consent should be obtained in written. By the same token, inadequate telemedicine tools cannot be imposed to the physician. It goes without saying that these requirements should be relaxed in emergency situations.
- Professional secrecy. The anonymity of the patient, the confidentiality of the personal medical records and the related communication, the staff's professional secrecy, the tracking of the medical acts performed should be ensured. The means to ensure professional secrecy should be clearly described in the contract governing the provision of telemedicine tools.
- Liability. Patients are responsible for the information provided. The physician is fully liable for the use he makes of this information. The telemedicine contract should identify clearly the identity of the patient, the "tele-experts" and the physician in contact with the patient.
- The physician practicing telemedicine on a usual basis should be bound by a contract compliant with the aforementioned criteria. The contract should include the usual functioning mode of telemedicine, the material used, modalities of information to the patient; and identity the physician consulted, the physician carrying out the act, as well as the means implemented to ensure professional secrecy. The contract should moreover be submitted to the Provincial Council of the Order of Physicians for opinion.

Article 33 of this Act compels regional health organizations plans to integrate telemedicine and to define operational modes to meet the requirements relative to public health and access to care.

3.6 Regulatory framework for electronic prescriptions

Article 34 of the Healthcare Insurance Act allows the prescription of care by email provided that the issuer can be identified and the integrity and confidentiality of the prescription is

[3] Dr. Deau X., Télémédicine, Report adopted by the National Council of the Order of Physicians during its session of July 2005, available at:http://www.coinseil-national.medecin.fr/?url=rapport/article.php&id=70

guaranteed. It is however required that a prior clinical examination of the patient has been carried out. Derogation is foreseen for emergency cases.
Another initiative should be mentioned. The creation of pharmaceutical records (Dossier pharmaceutique- DP-) was planed by law in early 2007 (new article L.161-36-4-2 of the Social Security Code) in connection with the DMP. Article L.4231-2 of the Public Health Code entrusts its implementation to the Order of Pharmacists. These records should allow pharmacists to share personal data related to the delivery of medicines in order to prevent dangerous medicine interactions. Their use and creation are facultative and subject to the prior consent of the patient who will be able to withdraw at any moment. The patient will be granted with a right of access that (s)he will be able to exercise via any pharmacists and with a right to object to the processing of some information. In the future, these records will be incorporate to the DMP.
An experimental project has been authorized by the CNIL on the 15 May 2007 which has allowed 400 pharmacies to create about 168000 records. The development of the software is financed by the Order of Pharmacists which plans to equip all pharmacies in a period of two years.[4] The government estimates that more than one million of DPs were created since the beginning of 2008.

3.7 Overview of relevant legislation

The numerous norms regulating health in France have been reorganised in 2002 via the reengineering of the Public Health Code (*Code de la santé publique*). This codification aims at clarifying and facilitating the access to legal norms for citizens and healthcare professionals. It contains a legislative and a regulatory part[5] meant to be comprehensive and to cover all aspects of medical law such as the rights of the persons (patients, participants to medical experimentations, etc.), the obligations of the physicians and other healthcare professionals, the rules applying to the delivery of medicines, etc. It fully integrates the Medical Code of Ethics in the regulatory part.
The following laws have introduced significant changes into the Code and will be referred to throughout this report:

- Act n°2002-303 of 4 March 2002 about sick persons' rights and the quality of the health system which has inserted into the Public Health Code two new chapters on the "rights of persons" and "the participation of users into the functioning of the health system". It details the ownership rights of the patient to his or her data, whereby transmission of personal information is authorised only between health professionals treating the same patient, and only with patient's prior consent (article L1110-4).

[4] Le Monde, Press release, Le Dossier pharmaceutique bientôt étendu à tout le territoire, 21 March 2008, available online at: www.lemonde.fr/web/recherche_breve/1,13-0,37-1029365,0.html

[5] For more info about the re-arrangement of the Code, please see Circulaire DGS/SD 4 A n° 2003-452 du 28 août 2003 relative aux trois premières parties (dispositions réglementaires) du code de la santé publique, available online at: http://www.sante.gouv.fr/adm/dagpb/bo/2003/03-40/a0403146.htm

- Act n°2004-806 of 9 August 2004 about public health policy
- Healthcare Insurance Act n°2004-810 of 13 August 2004. This law provides for the use of telemedicine, the creation of the Dossier Médical Personnel (DMP, Personal Medical Record), on behalf of the patient, in order to facilitate the continuity of care. A dedicated structure, the GIP (Public Interest Group) DMP, was created in April 2005 to design, supervise and organize the deployment of the DMP. Act n°2005-370 of 22 April 2005 about the rights of sick persons and at the end of their life.
- Act n°127-2007 of 30 January 2007 ratifying the Ordinance n°2005-1040 on the organisation of certain healthcare profession. Article 25 refers to personal medical file, the pharmaceutical file and the hosting of medical data. This decree introduces a new section in the Public Health Code relative to the confidentiality requirement applying to the storage and exchange of medical data.
- Decree n°2007-260 of 15 may 2007 on confidentiality of medical data stored on electronic support and electronically exchanged

Other relevant legislation for the development of eHealth comprises[6]:
• The Data Protection Act (Act n°78-17 of 6 January 1978 on Data Processing, Data Files and Individual Liberties), recently adapted to the provisions of the 95/46/EC Directive by the act of 6 August 2004 and which prohibits data processing without consent of the person, except for data absolutely necessary to the health professionals in charge of treating the person concerned, or those related to health service management or required by people exercising under professional secrecy. It moreover provides for strict rules governing the use of the national number as identifier.
• The ”Ordonnances Juppé” of 24 April 1996 organizing the secured electronic infrastructure for the system of reimbursement of healthcare, based on authentication of the insured persons and the health professionals as well as the usage of a secured network based on internet standards to exchange electronic information.

[6] March 2007 ERA Fact Sheet “eHealth strategy and implementation activities in France”: http://www.ehealth-era.org/database/documents/factsheets/France.pdf

4 Regulatory framework for the healthcare profession

4.1 Legal conditions for the practice of healthcare

The healthcare profession is regulated by different rules. The Public health Code distinguishes between medical professions (Physicians/Dental Surgeons/Midwives), pharmacists (which includes pharmacists' assistants) and medical auxiliaries (nurses, physiotherapists, chiropodists, ergotherapists, orthoptists, speech therapists, dieticians, medical radiology technician, hearing aid specialist, optician- spectacle manufacturer, prosthetist and orthesist for handicapped persons). It is worth noting that this excludes other professions usually part of medical teams such as psychologists, social assistant, etc.

The regulation of the education leading to the various professions in the healthcare sector in France is a competence of the Ministries of Education and Health. The educational programs are being modified in order to adapt to the Bologna process. This process is fundamentally affecting the structure of the studies.
Access to medical professions is regulated by the Public Health Code. Article L.4111-1 states that no person can practice as physician, dental surgeon or midwife if (s)he does not gather the conditions of diploma, nationality and registration into the Physician/Dental Surgeon/Midwives Order list. The legislator has progressively extended the possibility to practice medicine in France to citizens of the European Union and the EEA, as well as from third countries. Persons who do not satisfy these first two conditions can however be granted a specific authorization by decree issued by the Minister of Health.
In order to get their specialization, physicians can either get an official diploma issued by his University at the end of their formation, or when the formation has been followed outside the European Union or the physician whishes to practice a different specialization. In the former case, National Order to Physician registers the physician in the relevant list. In the latter case, the physician should obtain the approval of a specialized Commission formed by academics, members of professional trade unions and other members designated by the Order of Physicians and that evaluates the competences of the physician according to strict grid of specializations.[7]

The exercise of medicine is subject to the registration into the list of a provincial council of the competent Order. All professionals are subject to this obligation, included the healthcare professionals of the public sector. Only professionals from the army and civil servants are exempted. The registration is an administrative decision subject to the compliance with conditions of morality, independence, check of moral and physical capacity and a sufficient knowledge of French language (for more details and for the requirements concerning other

[7] Bulletin de l'Ordre des médecins N°2 Février 2008 page 4 : Vers un référentiel métier pour chaque spécialité

healthcare professions, see http://www.conseil-national.medecin.fr/?url=instal/article.php&offset=0).

This monopoly is exclusive, which means that with the exclusion of all others, physicians are competent to practice medicine. It is also all-embracing, which means that it covers every activity directed to cure, restore or put in order the body of the patient. It also includes preventive acts. The licit medicine acts are defined by a "nomenclature" adopted by a decree of the Ministry of Health based on the opinion of the National Academy of Medicine. Any person who usually or via following-up [*par direction suivie*], even in presence of a physician, would take part to the establishment of a diagnostic or treatment of sickness by any means or would practice one of the acts listed by the "nomenclature", without holding a diploma as required by article L. 4161-1 for the practice of medicine, would practice illegal medical acts. It not only concerns the physician but more generally any healthcare professional who would perform medical acts outside their own field of competence (Article L.4161-5).

Physicians can perform acts of care, i.e. related to diagnostic and treatment, but also investigations and preventive acts. The scope of competence of physicians has been substantially enlarged but at the same time other healthcare professionals have been granted similar competences. The monopole of prescription of physicians has moreover tended to be reduced. They now often share this prerogative with other healthcare professionals such as midwives, dental surgeons or nurses. This can be source of conflicts and confusion, more when professions of the health sector keep multiplying. Furthermore, the legislator not only enlarged the scope of acts reserved to healthcare professionals but also the main concept of healthcare professionals. As a way of example, the Law of 9 of August 2004 has broadened the competences of midwives who can perform examinations after "normal" pregnancy and deliveries.[8]

4.2 Control over the practice of medicine

The practice of medicine in France is supervised by the Order of Physicians. The Order includes all physicians who are permanently residing in France and who are inscribed on the list of the provincial orders. Nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in France without being registered on the list of the Order of Physicians (but need to notify their activities to the National Council of the Order of Physicians and to demonstrate a sufficient knowledge of French language). Although the person concerned in the latter case is not registered on the list of the Order, he will nevertheless be subjected to the jurisdiction of the Order for his activities on the French territory.

The most important function of the provincial councils of the Order of Physicians is to ensure observance of the rules of professional ethics for physicians and the upholding of the reputation, standards of discretion, probity and dignity of the members of the Order.

[8] Paragraph translated from , Laude A. et al, Droit de la santé, coll. Thémis droit, ed. PUF, 2007,p.388

The Code of medical ethics, established by the Order of Physicians, contains the rules concerning the general obligations of physicians (e.g., respect of individual dignity, professional secrecy, independence, morality, probity and, free choice of the physician, freedom in prescription of medicine), its obligations towards patients, towards other physicians and other healthcare professionals. It contains rules relative to the practice of the profession and is organized around four main general principles[9]:

- Primacy of the person. Physicians are to serve the individual before Public Health, except when this individual poses a threat to the collectivity. Physicians should respect human life, its dignity and the person. The most significant application of this principle resides in the obligation of secrecy, basis of trust.
- Freedom. This principle first relates to the freedom of the patient in choosing the physician, in accepting or refusing the treatment proposed by the physician (who has a stronger obligation of information to the patient). It also relates to the freedom of the physician who is compelled to provide care to persons who need it, to behave with morality, probity and dedication to his profession. The physician is free to prescribe medicines however subject to the availability of public resources. This freedom grounds the healthcare contract.
- Quality. Physicians are personally liable for their acts, with the correlative obligation to maintain their independence. Physicians should be competent, meaning that they hold the degree(s) required but also have to follow complementary and permanent formations. They should finally be available to and do not discriminate patients. Equity is required for certain patients who are in a weakened position.
- These principles are translated in a series of practical rules for the practice of medicine towards patients and other physicians and healthcare professionals.

The code is approved by decree adopted by the State Council and as such has been integrated to the Public Health Code, in the regulatory part. The order of Physicians can impose a disciplinary sanction to the physician who has infringed a rule of the Code. It is the only authority to state on disciplinary sanctions, being however possible to appeal to the State Council [*Conseil d'Etat*]. It is moreover worth noticing that since the mid-nineties, civil and administrative jurisprudences make a growing use of the code of medical ethics to ground civil or penal faults.
Professional Orders with similar competences exist for Dental surgeons, midwives, pharmacists, nurses, physioterapists and chiropodists.

The evaluation of professional practices

The evaluation of the professional practices of a Physician consists in the analysis that the physician, in collaboration or not with his peers, does about his clinical activity on basis of recommendations on good practices formulated by the High Health Authority (Haute

[9] Conseil National de l'Ordre des Médecins, Introduction aux commentaires du Code, available online (in French) at: http://www.conseil-national.medecin.fr/?url=deonto/rubrique.php&open=0#0

Authorité de Santé). This approach is inspired from the British 'formative assessment'. Physicians commit not only to base their practice on a series of recommendations but also to evaluate and assess their practices according to these recommendations on a regular basis. This should eventually result in an improvement of practices in the interest of the patient. In that sense the National Order of Physician advocates for the fusion and for bridging this procedure with the medical permanent formation as both follow the same approach. It intends to simplify procedures and facilitate the registration of new physicians.

4.3 Professional liability[10]

Since 1990, jurisprudence has increased healthcare professionals' liability creating new obligations or strengthening existing ones. The Act of 4 March 2002 intended to fix this evolution, crystallizing the jurisprudential evolution, and to install a framework for medical liability. Aiming to recognize rights and duties to patients, this law however opts for principles that often stay aback from jurisprudential advances and thus fails to satisfy healthcare professionals. It moreover reduces significantly the period of statute limitation, now established in 10 years.

Since an important ruling of the French Supreme Court of 20 May 1936, the so-called "Mercier judgment"[11], the relationship of the physician and the patient is qualified as contractual relationship and thus subject to general civil liability rules. This ruling has also defined the nature of the obligation of the physician who does not have the obligation to cure the patient (obligation of result) but to provide him/her careful and adequate care (obligation of means). It further recognizes that medical acts are by nature unpredictable given that their results depend on a series of uncontrollable factors, e.g. the sufferance of the patient to the treatment, the apparition of secondary effects, the nature of the sickness itself. The commission of a fault by the physician should thus be proved to engage his liability.

In the public sector, the patient is however considered as user of a public service and as such subject to the general State's liability rules as defined by administrative law.

The Law of 4th May 2002, following the jurisprudence, has however introduced two cases of faultless liability: for damages caused by contagion in a health establishment and by defective health products. The victim has only to demonstrate that the damage has been caused by the physician during the performance of the medical act. Contagions in a health establishment are however automatically repaired by the National Office of medical accident reparation (*Office national d'indemnisation des accidents médicaux*) whenever they have provoked an incapacity superior to 25% or the death. In these specific cases, the health establishment remains liable if a fault is at the origin of the damage. With regard to defective products, the jurisprudence had recognized an obligation of "security-result" of producing a device without

[10] Section based on Maître ANAHORY, *Etude de la responsabilité liée à l'introduction du dossier médical personnel*, 2005, available online at: http://www.d-m-p.org/index.php?option=com_content&task=view&id=31&Itemid=211; DORSNET-DOLIVET A., La responsabilité du médecin, coll. Pratique du droit, ed. Economica, 2006; and SAISON-DEMARS J., *Fasc. 229-50: Droits des personnes malades et autres usagers du système de santé*, JurisClasseur Administratif, 15 November 2006.

[11] Supreme Court, Civil Chamber (Cass. Civ.), 20 mai 1936, DP, 1936, I, 88, concl. Matter.

default, on the basis of the law on defective products transposing the European Directive. This covered any device used by the physician when performing a medical act. However, some scholars wonders whether this specific obligation would survive to the new wording of the Law of 4 March 2002 which subjects the application of article L.1142-1 I to the conditions of liability as defined by the Law of 19 May 1998 on defective products.[12]
It is worth mentioning that since 1992, the administrative liability regime has been relaxed and a simple fault is sufficient to engage the liability of the public hospitals[13]. With regard to private hospitals, the jurisprudence has established that these establishments are liable for their staff.[14] A hospitalization contract is concluded between patient and the clinic, being the latter contractually liable for third parties' acts towards the patient. This regime does not however apply to private hospitals or when a serious fault can be distinguished from the service. Civil judges would then be competent to determine the liability of the physician. Finally, depending on the seriousness and nature of the fault, the liability of the physician can also be engaged on a penal and disciplinary (infringement of the code of ethics) basis.

4.4 Professional secrecy [15]

The breach of professional secrecy could imply a penal (Art. 226-13 Penal Code) but also a disciplinary sanction16 which could go together with administrative or civil liability.

Article 226-13 of the Penal Code states that "the disclosure of secret information by a person entrusted with such a secret, either because of his position or profession, or because of a temporary function or mission, is punished by one year's imprisonment and a fine of €15,000". This article thus implies in first place that the person entrusted is depositary of a secret. In that sense, article 4 of the Medical Ethics Code compels physicians to secrecy about any information they would have access to during the practice of their profession, i.e. "not only the information (s)he has been told but also anything (s)he would have seen or understood (Public Health Code, article R.4127-4)". In order to comply with this obligation they must ensure that their assistants are made aware of their professional secrecy obligation and comply with it.] More recently, the Act n°2002-303 of 4 March 2002 has extended the professional secrecy to healthcare professionals and professionals participating in the health system (new article L.1110-4 of the Public Health Code).
It covers any information accessed to during their activities. It also defines this obligation as a right of the patient and an obligation for the healthcare professional.

[12] Dorsnet-Dolivet A., La responsabilité du médecin, coll. Pratique du droit, ed. Economica, 2006, p. 212-213.

[13] State Council (CE), Assembly, 10 April 1992, *Epoux V.*

[14] See for instance, Civ. 1e, 9 novembre 2004, (01-17.168 for midwives and 01-17-908 for surgeons) ; D. 2004, inf. rap. p. 3039; JCP 2004, IV, 3452 et 3453 ; Gaz. Pal. 14 November 2004, p.34 ; Revue Lamy Droit Civil, December 2004, p. 21.

[15] Section based on Maître ANAHORY, *Etude de la responsabilité liée à l'introduction du dossier médical personnel*, 2005, available online at: http://www.d-m-p.org/index.php?option=com_content&task=view&id=31&Itemid=211; SAISON-DEMARS J., *Fasc. 229-50: Droits des personnes malades et autres usagers du système de santé*, JurisClasseur Administratif, 15 November 2006.

[16] State Council (CE), 29 December 2000, G.: Juris-Data n°2000-149274; Rec. CE 2000, p.676.

Secondly, article 226-13 of the Penal Code implies a information being 'secret'. The source of the information, the content of the secret and its limits should thus be defined. Jurisprudence has recognized medical secrecy as general and absolute[17]. It follows that professional secrecy covers any disclosure of information in oral or written form[18], made to another professional also subject to professional secrecy[19], harmful or not[20]. In that sense and as mentioned above, the secrecy of article 4 of the Medical Ethics Code includes not only the information (s)he has been told but also anything (s)he would have seen or understood. The new article L.1110-4 of the Public Health Code specifies that the secret covers all information related to the person that the healthcare professional gets to know. The obligation of secret is limited to the relation healthcare professional-patient and to the information gathered during this relationship. But it is irrelevant whether the information was already publicly known or not.

Patients can not relieve their physician from his professional secrecy.[21] This means that even if the patient consents to disclose the information protected by the secret, the physician is not allowed to do so and would be sanctioned if he would. The obligation thus does not disappear with the death of the patient.[22] Physicians are entitled not to testimony when it concerns facts protected by professional secrecy, despite the prior consent the patient.

Finally, the disclosure of the secret should have been intentional, i.e. the physician should be aware that he is disclosing a secret. Misfeasance or negligence does not allow for penal prosecution.

Article 226-14 of the Penal Code relieves the healthcare professional from professional secrecy in cases where the law authorizes or imposes the disclosure of secrecy. For instance, the Law of 4 March 2002 explicitly acknowledges the "share secrecy" between two or more healthcare professionals or a medical team in a hospital or clinic. When the patient is followed-up by a medical team, the medical information is presumed to be provided by the patient to the whole team. However, in any other cases, strict conditions subject the sharing of medical information: the patient, duly informed, should not have opposed to such sharing; the sharing can only pursues the aim of ensuring the continuity of the care or to defining the best care to be provided.

Article 226-14 of the Penal Code moreover allows derogation to professional secrecy to inform certain public authorities for needs or prosecution or specific offences and crimes. Family and relatives of the patient can also be informed of relevant information (and not of all

[17] Supreme Court, Criminal chamber (Cass.Crim.), 19 déc. 1885, Watelet et Crim., 8 mai 1947, Decraene.

[18] Supreme Court, Criminal Chamber (Cass. Crim.), 19 December 1885, W.:S 1886, 1, p.86, about letters: State Council (CE) 1st June 1994, n°150870, CHS Le Valmont: Juris-Data n°1994-048882 about information provided by a nurse from the psychiatric sector to a moviemaker which has allowed him to contact the patient.

[19] Supreme Court, 1st Civil Chamber (Cass. 1ere civ.) 12 January 1999: Bull. Civ. 1999, I, n°18, about a letter relative to a patient sent by his physician to an Insurance company.

[20] Supreme Court, 1st Civil Chamber (Cass. 1ere civ.), 14 December 1999, n°97-15756: Bull. Civ. 1999, I, n°345 about the revelations made by Doctor Gubler after the death of President Mitterrand.

[21] State Council (CE), 28 May 1999, n°189057, T.: Juris-data n°1999-050370; Rec. CE 1999, p.159, about a physician that authorises, with the prior consent of the patient, the dissemination in the press of her picture within an investigation about hypnosis

[22] Supreme Court, 1st Civil Chamber (Cass. 1ere civ.), 6 January 1998: Bull. Civ. 1998, I, n°3

the information contained in the medical records)[23] in specific cases, e.g. in case of "serious diagnostic or prognostic" provided that the patient did not opposed to it.

Article L.1110-4 of the Public health Code moreover introduces a new incrimination consisting in obtaining or trying to obtain the communication of medical information breaching the professional secrecy. The Code of Ethics compels physicians to protect medical data against any disclosure, irrespective of the carrier on which these documents are recorded (Health Public Code, art. R 4127-73). They must protect medical documents against any breach of confidentiality. This provision is particularly relevant with regard to the computerization of the personal medical file. Article L.1111-8 of this Code authorizes the deposit of health personal data to certified host providers, prior express consent of the data subject and in conformity with the Data protection Act. It is worth noting the obligation made to host providers to have a physician within their staff. This obligation raises a number of questions, in particular with regard to the fact whether his access to the data are covered by the professional secrecy.
Understood as prerogative of the patient, professional secrecy is not opposable to him[24] except in case where it contributes to patients' interests or other legitimate motives (Art. 35 of the Code of Ethics; art. R.4127-35 of the Public Health Code).
The Healthcare professional has an obligation to give a free access to all health data related to the patient. Two derogations are foreseen: when a third party would be exposed to a risk or when the patient wishes not to be informed of a diagnostic or a prognostic.

[23] State Council (CE), 26 September 2005, n°270234, Conseil nat. Ordre médecins : Juris-Data n°2005-068951; Rev. gén. Dr. méd. 2006, p.379, chron. J. Saison)
[24] Supreme Court, 2nd. Civil Chamber (Civ. 2e), 28 janvier 1966 : Supreme Court, Criminal Chamber (Crim.), 24 April 1969 ; Supreme Court, Social Chamber (Soc.), 1er mars 1972. CE, 11 February 1972.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 1978 France has general legislation protecting the individual with regard to automatic processing of personal data. The Act n°78-17 of 6 January 1978 on data processing, data files and individuals liberties has been recently amended (2004) in order to transpose the provisions of the European Directive 95/46/EC.[25]

Generally speaking the French data protection Act is very similar to the European directive. Directive 95/46/CE has been transposed in France after a delay of almost 10 years. This delay is mainly due to the will of the French legislator to maintain a high level of protection without substantially affecting the existing legislation. To that effect, the project of modification prepared by the French government has been based on the conclusions of the Report of Guy Braibant. This report recommended modifying the format of the existing Law without affecting the substance of the Law which had inspired the drafters of the Directive. This has finally resulted on the adoption of the Law n° 2004-801 of 6 August 2004.[26]

It seems important to highlight the following differences[27]:

- Definitions of the essential concepts:
    - "personal data": French Law does not include the list of examples contained in the Directive;
    - "controller": French Law does not include the notion of a "co-definition" by several controllers of the means and finality of the processing. The legislator pretended to avoid legal conflicts in case of multiple controllers and issues stemming from the sharing of liability between several controllers;
    - "Processor" and "consent" are not defined by the French Law. With regard to the latter, it is thus necessary to refer to general rules to define the conditions the consent should meet (for further evidence). A first consequence is that the controller cannot rely on the silence of the data subject if it cannot demonstrate the existence of consent.
- The criteria for making personal data processing legitimate (art. 7 of the Directive) are likely to the Directive. The French legislator has however transposed the derogation based on the performance of a task carried out in the "public interests" into "the performance of a mission of public service".

[25] An English version of the consolidated Act is available at: http://www.cnil.fr/fileadmin/documents/uk/78-17VA.pdf

[26] PERRAY R., Fasc. 274 – Informatique.- Traitement de données à caractère personel, JurisClasseur Administratif, 31 January 2008.

[27] PERRAY R., Fasc. 274 – Informatique.- Traitement de données à caractère personel, JurisClasseur Administratif, 31 January 2008

- The legislator did not make use of the possibility given by the Directive to enhance the level of protection of data relative to administrative sanctions which are not considered as sensitive data.
- Authorization regime. The French Law foresees a series of 8 kinds of processing that should be subject to the prior authorisation of the CNIL. Processing of sensitive, genetic or biometric data are for instance subject to prior authorisation. "Linked processing" with distinct finalities and held by different legal persons are subject to prior authorisation as well.
- Security and confidentiality information. French law states (art. 34) that the controller shall take all useful precautions, with regard to the nature of the data and the risks of the processing, to preserve the security of the data and, in particular, prevent their alteration and damage, or access by non-authorized third parties, and makes no reference to "accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access" as does article 17 of the Directive. French law moreover holds the controller liable for the non-respect of security and confidentiality obligations by the subcontractor and punishes security breaches with penal sanctions.
- The data subject's rights (art. 12, 14 and 15 of the Directive) : French legislation added a specific provision on access to health data (see further) and provides for derogation installing the so-called "indirect access" where processing involves State security, defence or public safety. Moreover, the charge of the proof of the rectifications and cancelation requested by the data subject bears upon the controller.
- French law makes use of the possibility let by article 18 of the Directive for controllers to appoint a data protection officer. Controllers which do so are exempted from their obligations of notification.

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

French law contains separate provisions for a) sensitive personal data (= all data mentioned in art. 8.1 of the Directive), b) data concerning offences, convictions or security measures. As far as medical data are concerned, two additional chapters of the Laws introduce specific provisions for the processing of personal data for the purpose of medical research (Chapter IX) and of evaluation of analysis of care and prevention practices or activities (Chapter X).

Art. 8 of the French law regulates the processing of sensitive data and is formulated as follows:

"I.- The collection and processing of personal data that reveals, directly or indirectly, the racial and ethnic origins, the political, philosophical, religious opinions or trade union affiliation of persons, or which concern their health or sexual life, is prohibited.

II.- In so far as the purpose of the processing may so require in respect of certain categories of data, the prohibition provided for in Section I shall not apply to:
(1) processing for which the data subject has given his express consent, except in cases where the law
stipulates that the prohibition provided for in Section I may not be lifted by the consent of the data subject;
(2) processing necessary for the protection of human life, but to which the data subject is unable to give his consent because of a legal incapacity or physical impossibility;
(3) processing carried out by an association or any other not- profit-seeking religious, philosophical, political or trade union body:
- only for the data referred to in Section I corresponding to the object of that association or body;
- if it relates only to members of this association or body and, when appropriate, individuals who have regular contact with it in connection with its activity;
- and that it relates only to data not transmitted to third parties, except where the data subjects expressly consent to such transmission.
(4) processing that relates to personal data that the data subject has made public;
(5) processing that is necessary for the establishment, exercise or defense of a legal claim;
(6) processing that is necessary for the purposes of preventive medicine, medical diagnosis, provision of healthcare or treatment, or for the management of healthcare services and carried out by a member of a medical profession, or by any other person who, due to his functions, is bound by a duty of confidentiality as stipulated in Article 226-13 of the Criminal Code;
(7) statistical processing carried out by the National Institute of Statistics and Economic Studies (INSEE) or one of the statistical services of Ministries in conformity with Act No. 51-711 of 7 June 1951 relating to obligations, co-ordination and confidentiality as regards statistics, following an opinion of the National Council for Statistical Information (CNIS) and in accordance with the conditions provided for in Article 25 of this Act [*authorization by the CNIL]*;
(8) processing necessary for medical research according to the conditions provided for in Chapter IX [*processing of personal data for the purpose of medical research]*.

III.- If the personal data mentioned in Section I are, within a short period of time, to be subject to an anonymisation procedure which the "Commission nationale de l'informatique et des libertés" has earlier approved as complying with the provisions of this Act, the Commission may authorize certain categories of processing according to the conditions stipulated in Article 25 [*authorization by the CNIL*], taking their purpose into consideration. The provisions of Chapter IX [*processing of personal data for the purpose of medical research*] and Chapter X [*processing of personal medical data for the purposes of evaluation or analysis of care and prevention practices or activities*] shall not apply.

IV.- Likewise, an automatic or non-automatic processing shall not be subject to the prohibition provided for in Section I when it is justified by the public interest and authorized within the conditions stipulated in Section I of Article 25 [*authorization by the CNIL]* or in

Section II of Article 26 [*authorization by a decree in Conseil d'Etat after a reasoned and published opinion of the CNIL]*.

The following comments can be made with regard to art. 8 of the French law:

- The concept of medical data should be understood broadly as including all information related to the health of a person either psychic or physical, including genetic *data (see* Senate, Report n° 218, p. 60, following the Recommendation of the Council of Europe R(97)5 of 13 February 1997)
- Medical data can only be processed with the express consent of the data subject. The express consent is not required for the needs of preventive medicine, medical diagnostics, the provision of care and treatment and the management of health systems. French law makes here a close transposition of the Directive. It does however not provide additional indications on the criteria required for the consent to be deemed « express ».
- The CNIL can authorise, on the basis of their purpose, processing making use of sensitive data such as medical data, provided these data are anonymised. The anonymisation process should be based on an algorythm codifying data such as the name, surname, gender or date of birth by a unic number reproductible but should not be reversible.
- Prior authorization of the CNIL (Commisssion Nationale de l'Informatique et des Libertés -French data protection authority) is required for automatic processing of genetic data, unless carried out by physicians or biologists and necessary for preventive medicine, medical diagnosis or the administration of care or treatment (Article 25).
- The High Authority for Health [*Haute autorité de santé*] created by the Healthcare Insurance Act of August 2004 is in charge of defining a certification process of websites dedicated to Health and of software helping to medical prescription. The certification will be carried out by a body accredited by this Authority. To that effect, this authority cooperates with the Swiss foundation Health On the Internet (HON) which certifies websites providing health information from 1996. To get certified, the website should comply with a Code of Conduct developed by HON and which is evaluated by the foundation. Once certified, the website is entitled to use of specific seal that informs Internet users. The certificate should be renewed on a yearly basis.[28]

5.3 Information and access rights of data subjects[29]

Article 43 of the French Data Protection Act introduces specific rules for the access of the data subject to medical data. The data may be disclosed to the data subject directly or through

[28] http://www.has-sante.fr/portail/upload/docs/application/pdf/internet_sante_info_editeurs.pdf

[29] Based on Commission Nationale de l'Informatique et des Libertés, L'accès au dossier medical, 8 November 2004, available online at: http://www.cnil.fr/index.php?id=1330

a physician that (s)he designates for this purpose, in conformity with the provisions of Article L1111-7 of the Code of Public Health.

The Law of 4 March 2002 has introduced the principle of direct access of patients to their medical data. The decree of 29 April 2002 has organized this access. However, patients keep their right, if they wish so, to access their data through the physician. The physician may require the presence of a third party but cannot prevent a direct access to the data in case the data subject refuses.
The access can be requested to the physician or the health establishment by data subjects, their heirs, parental authority owners, the tutor or the designed physician.
The data should be communicated in a maximum delay of 8 days from the day following the request and at the earliest after 48 hours (cooling off period). When information is older than 5 years (from the moment of the information has been recorded), this period is extended to 2 months.

The data subject shall be given access to all information relative to his health, i.e. all information recorded and that have contributed to the elaboration and follow-up of the diagnostic and the treatment or an action of prevention; or have been exchanged in written between healthcare professionals, in particular examinations results, consultation, intervention, exploration or hospitalization reports, protocols and therapeutic prescriptions carried out, surveillance sheets, correspondence between healthcare professionals, except when it is mentioned that they have been collected from third parties not intervening in the care treatment or are relative to a third party. The carrier on which the information is being stored does not affect the content of the right.

The communication should be done in a clear language, meaning for example that the physician should indicate the signification of the codes used.

A minor can oppose his data to be communicated to his legal representatives by the physician. The physician should then indicate such opposition in written in the file. In case the legal representative formulates a request of access, the physician should try to obtain the consent of the minor but if the minor maintains his opposition, the request should be refused.

The successors can access to information relative to the dead person insofar these data are necessary to understand the causes of the death, to defend the memory of the dead person or to defend his rights, except if the dead person has previously opposed to it. The successor should indicate the motive of his request. Any refusal to the request should be motivated.

When the data subject is hospitalized ex officio or upon the request of a third party, the controller can decide that the disclosure should take place via a physician. In this case, he informs the data subject. If the data subject refuses to designate a physician, the controller or the data subject can appeal to the provincial commission of psychiatric hospitalizations whose decision is binding.

In case access would be denied, the patient could file a complaint to the CNIL or a judicial complaint in case it concerns self-employed health professionals, or to the Commission for accessing administrative documents (*Commission d'accès aux documents administratifs* - CADA), before going to administrative courts. It is worth noticing that the CADA has extended the access to the personal notes of the health professional insofar these notes participate to the establishment of a diagnostic.[30] This extensive interpretation has been followed by the Administrative Appeal Court of Paris.[31]

5.4 Electronic health records

The Healthcare Insurance Act provides for the creation of Electronic Health Records, the so-called "Dossier Médical Personnel" (DMP, Personal Medical Records), on behalf of the patient, in order to facilitate the continuity of care, the coordination between healthcare professional and to avoid redundant acts. The DMP constitutes a central point of the reform operated in 2004 which pursues four main objectives: strengthening of the coordination of health stakeholders; collection of data allowing a better evaluation of patients' health condition; improvement of health professionals' practices; and making patients aware of their responsibilities.[32]

A dedicated structure, the GIP (Public Interest Group) DMP, was created in April 2005 to design, supervise and organize the deployment of the DMP. It should, amongst others, define the data related to prevention, diagnosis or care that should be include into the DMP, conditions of hosting, access and transmission of the data. The decree n°2006-6 of 4 January 2006 has defined the conditions for the certification of host providers. Certification procedures have been hold for a period of three years, for the approval of reference practices for security and interoperability based on international standards by the Ministry of Health. The effective deployment was planned in 2007 by the Law but this delay proved to be unrealistic in view of the importance of the task to be done. However, experimental testing has been carried out in 13 departments with voluntary patients during the year 2006 with prior authorization of the CNIL[33]. The objective was to test the feasibility and level of acceptation of the DMP. Patients were given the possibility to "mask" some information. A unique access point to the DMP should be created to provide general information, to facilitate to patients the management of their DMP and to manage the access rights of health professionals.

Two reports have been commissioned by the Parliament (Report DOOR, January 2008) and by the Government (Report GAGNEUX, April 2008) in order to identify and analyse the obstacles to the implementation of the DMP and to define a new roadmap for its implementation. This requires to ensure the complementarity of the DMP with other initiatives such as the Pharmaceutical Dossier, and to make sure that it fulfils its role of ensuring the continuity, the

[30] CADA, Council of 15 april 2004, n°20041645

[31] Administrative Appeal Court of Paris, 30 September 2004, n°03PA01769, Ulla G.

[32] ANAES, Rapport au ministre de la santé sur les conditions et modalités de mise en oeuvre du Dossier Médical Personnel

[33] Deliberation of 30 May 2006.

coordination and the quality of care within the health information infrastructure. Both reports insist on the need to conceive the DMP as a tool for healthcare professional and to adopt a step-by-step approach for its implementation.
Finally, it should be referred to the report of the National Committee of Ethics has however recently (29 May 2008) on the risks linked to the DMP, under the petition of the Ministry of Health, and has conclude to the doubtful ability of the DMP to meet its goals with its current characteristics. In particular, it recommends limiting the deployment of the DMP to patients that have specific needs for it or have understood the objective of such records, on a voluntary basis.[34]

5.4.1 Characteristics of the DMP

Article L. 161-36-1 of the Social Security Code specifies that the DMP contains the personal data collected or obtained during preventive, diagnostic or care activities, and more generally any information that allow the follow-up of the provision of care, included prevention acts. Medical files created by health institutions should already contain the identification of the patient; each written act, dated and identifying the healthcare professional who performed it; each prescription, time stamped and signed by the health professional who issued it, duly identified.
Each healthcare professional must report the diagnosis or therapeutic elements to the DMP after performing a medical act or consultation. The law moreover subjects the application of conventions between health professionals and the Social Security to the consultation and update of the DMP. The healthcare professional should moreover specify on the reimbursement form that (s)he has been able to access the DMP. Healthcare professional employed by a health establishment should report a summary of the stay of the patient. This creates an obligation for health professionals to create and up-date a DMP for each patient. This record is likely to be converted in the new mandatory tool to report information related to the patient. Several points are however still pending of definition: the exact list (and nature) of health data to be included or the persons compelled to its follow-up and update.

Patients have the obligation to present their DMP to the healthcare professional. They however keep the right to refuse the healthcare professional to access the DMP but then would obtain worse reimbursement's rates. This economical sanction puts at stake the principle of prior consent pointed out by the CNIL as a core principle of the system. Moreover, healthcare professionals are entitled to access the DMP without the prior consent of the patient in case of emergency, except if the patient has previously opposed to such access. Access to the DMP by other healthcare professionals, e.g. of a medical team, are subject to the prior consent of the patient. In accordance with the guidelines given by the Minister of Health that advocate for the relief of the patient from this obligation, the report

[34] Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé, Opinion n°104, Le dossier medical personnel et l'informatisation des données de santé, 29 May 2008, available online at: http://www.ccne-ethique.fr/

GAGNEUX recommends that the DMP should be presented by patients to healthcare professionals on a voluntary basis.

The possibility granted to the patient to refuse the access to the DMP does not mean that the healthcare professional cannot include this information into his own medical records. Moreover, some elements of the medical records remain restricted from the right to information of the patient: the personal notes of the healthcare professional (with the aforementioned exceptions acknowledged by CADA and administrative jurisprudence); the information collected towards third parties which do not intervene in the therapeutic follow-up; the information not formalized and that cannot be included in the records.

Moreover, healthcare professionals are granted with a limited access to the DMP according to their field of competences and the act they are to perform. To that effect, a decree adopted in State Council [*Conseil d'Etat*] after opinion of the CNIL and the national councils of health professional orders, should define the conditions of access to the categories of information contained into the DMP, the conditions under which certain information can be masked by patients or their legal representatives and how the healthcare professional obtain knowledge from the existence of masked information.
Finally, the DMP can not be consulted by third parties for other purposes than the ones defined to Article L. 161-36-2 even with the prior consent of the data subject. More specifically, the access is prohibited for the conclusion of any contract requiring the evaluation of the health condition of the user. It cannot be consulted either by the occupational physician. The commercialization of health data are moreover sanctioned by the Penal Code (Article 226-21).

5.4.2 Obligations made to host providers

The DMP is created by a certified host. Article L.1111-8 of the Public Health Code compels healthcare professionals to "deposit the personal data, gathered or produced during prevention, diagnostic or care acts into [the systems] of accredited physical and legal persons." The deposit should be governed by a contract with the host provider. Medical data host providers and their staff are subject to the same professional secrecy as protected by article 226-13 of the Penal Code.
The deposit is subject to the prior and express consent of the patient. Derogation is foreseen to allow healthcare professionals to use their own information system to store the medical records provided that the access is restricted to the sole healthcare professional or institute and to the patient. Article L.1111-8 of the Public health Code explicitly specifies that such processing is subject to the provisions of the Data Protection Act. They are moreover subject to the specific provisions on professional secrecy and to conditions of interoperability of systems as defined by the Ministry of Health.
Host providers must process the data with the sole purpose of the maintenance of the DMP, they cannot transfer the data to other healthcare professionals or institutes and must transfer

the data to the healthcare professional or institute or data subject counterpart of the contract initially signed.
Article R. 1111-9 defines the conditions for the certification of host providers. They should in particular prove their professional competence, define their confidentiality and security policy, identify their representative established in France, separate the activity of medical data hosting from other activities of hosting, define the information process due to person who has originally deposit the data and finally identify the person in charge of the hosting, in particular the physician part of the team. The certification is delivered for a period of 3 years by the Ministry of Health after prior opinion of the CNIL and the certification committee. The core mentions of the host contract and of the confidentiality and security policy are defined by articles R.1111-13 and R.1111-14.

5.5 Other relevant rules regarding personal data protection

Detailed provisions in the implementation of the French data protection law regulate the further processing of personal data for medical research purposes. Because these rules are not directly relevant for cross-border interoperability of eHealth services, they are not further explained in this report. More relevant are the legal provisions about the use of the national number, also called "social security number", in the medical sector.
Every individual born in the French territory or who becomes a beneficiary of the French Social Security is attributed a registration number (NIR - *numéro national d'inscription au répertoire des personnes physiques*). The NIR is a meaningful identifier. It is based on a chain of character that allows determining the gender, date and place of birth of the individual (Art. 4). It is highly reliable insofar it is certified by the INSEE on the basis of the civil status information sent by the municipalities.
Because of these characteristics, the NIR is a convenient identifier to link databases. The Data Protection Act however restrains the use of the NIR and of data matching processing to a previous authorisation given either by the CNIL (Art. 25.6°), by legal provisions, or by regulatory provisions taken after the (non-biding but public) opinion of the CNIL (Art. 27.1°) and under the control of the State Council (*Conseil d'Etat*)[35]. The infringement of these provisions is punished by five years of imprisonment and a fine of 300,000 euros (Art. 226-16-1 of the Penal Code). The RNIPP is currently and mainly used, apart from Social Security agencies, by Fiscal Agencies, the National Bank, and by the INSEE for the administration of the companies' directory (SIREN) and of the electoral file.
The use of the NIR as "health identifier" for health medical records such as the DMP and the Pharmaceutical Records has triggered public debate. Article 25 of the Act n°2007-127 of 30 of January 2007 provides for the creation of a specific identifier for health medical records without specifying how this identifier should be formed. The CNIL has opposed to such use due to the sensitivity of the medical data which call for reinforced safeguards, incompatible with the risks of using an identifiers largely known by several stakeholders. It would require not only the implementation of specific measures of protection but would also risk altering the

[35] The State Council is the highest administrative jurisdiction in France. It ensures the legal validity of administrative acts.

trust between healthcare professionals and patients. The CNIL has proposed a more balanced approach based on the creation of a specific and meaningless identifier for health data, generated from the NIR but according to certified procedures of anonymization. [36] According to the CNIL the creation of a new identifier would allow to take benefit from the advantages offered by the NIR at the time it would maintain a high level of protection.

[36] CNIL, Conclusions on the use of the NIR as health identifier [*Conclusions sur l'utilisation du NIR comme identifiant de santé*], 20 February 2007, available at: http://www.cnil.fr/index.php?id=2197&news[uid]=434&cHash=dd6d3df873

6 Rights and duties of healthcare providers and patients[37]

The rights and duties of healthcare providers and patients are regulated in the law on the rights of patients and of the quality of the healthcare system of 4 March 2002. This Law introduces two new chapters in the Public Heath Code, respectively dedicated to "the rights of persons" and "the participation of users in the health system". The provisions of this law have been defined by jurisprudence and completed by other legislative provisions such as the Law of 9 August 2004 about health policy, the healthcare insurance Act of August 2004 and the Law of 22 June 2005 about rights of patients at the end of their life.

6.1 Scope of the Code

The Law of 4 March 2002 does not refer to "patient" but to "persons" and establishes a series of right when these persons are subject to a medical act. The denomination participates from the desire to establish a "health democracy" ("démocratie sanitaire") where the person should actively take part to his health and to the health system. The person is granted with rights and obligations. The objective is to make patients aware of their responsibilities.

Healthcare means "the services that a health professional provides in order cure, restore or preserve of a patient."

Health professionals in the current state of the legislation are: physicians, surgeon dentists, midwives, pharmacists, physiotherapists, nurses, paramedics and medical assistants and dieticians.

6.2 Rights and obligations of patients

6.2.1 Right to the protection of health

The right to the protection of health is recognized in the first article of the Public Health Code and has been granted with a constitutional value.[38] Any person can benefit from this protection either at individual or collective level. It forbids anyone to cause harm to the health of others and compels the State to take any measure necessary for the protection of individuals' health. It includes a right to prevention, an in particular the right to preventive acts acknowledged as care acts (Article 111-7), the right to equal access to care and the right to continuity of care which means not only the collaboration between patients and healthcare providers but also the communication, coordination, adequacy convenience and coherence of care. The coordination is ensured via health networks whose existence has been established by the Law of 4 March 2002 and aims to facilitate access to care and its continuity.

[37] This section is based on Laude A., Mathieu B. and Tabuteau D., Droit de la santé, coll. Thémis droit, ed. PUF, 2007; and SAISON-DEMARS J., *Fasc. 229-50: Droits des personnes malades et autres usagers du système de santé,* JurisClasseur Administratif, 15 November 2006.

[38] Constitucional Court, 15 January 1975, DC, law about abortion.

6.2.2 Non-discrimination principle

Article L.1110-3 of the Public Health Code states that no one can be discriminated in the access to prevention or to care. This principle prohibits unjustified discriminations on basis of origins, gender, familial situation, health condition, handicap, morals, race or religion. It stems from the general principle of non-discrimination sanctioned by the Penal Code (Art. 225-1).

6.2.3 Right to the quality of care

Article L1110-5 introduces the right of every person to receive care and therapy appropriate to his health condition and with recognized efficiency and to receive emergency treatment whenever required. This article has based the definition of the reference practices which ensure that medical practices correspond to processes regarded as optimal. This article also bases the obligation for healthcare professionals to ensure their continuous formation and their evaluation. It moreover provides for an efficient organization of the healthcare system and its structures.
Finally this right implies that the healthcare professional does not put patients under excessive risks with regard to the expected benefit on the basis of the medical state of the art.

6.2.4 Right to dignity

Patients have the right to dignity (Article L.1110-2). Dignity is the basis for the recognition of the right to be informed of the risks triggered by the performance of a medical act or to receive care aiming at reducing the pain (article L.1110-5). This principle has recently been extended to person “at the end of life” by the Law of 22 April 2005. This law has added the obligation for healthcare professionals to do as much as possible to ensure persons’ dignity until their death. It introduces procedures for limitation or cessation of treatments on basis of the requirement of transparency and collective decision of the medical team.

6.2.5 Right to the respect of human body

The principle of unavailability of the human body has been recognized by the bioethics laws, namely the law of 29 July 1994 relative to the human body (which has inserted a new article 16 in the Civil Code). Derogations are however foreseen in case of medical necessity or when a therapeutic interest of a third person requires it.

6.2.6 Right to privacy

Article 9 of the Civil Code protects the right to privacy. One of the aspects of this right is the protection of the intimacy of the patient. On the basis of this article the jurisprudence has protected not only the image but also the room of the patient. The Law of 4 March 2002 has introduced a new article L.1110-4 in the Public Health Code that recognizes the right to the respect of private life of any person treated by a healthcare professional.

6.2.7 Right to free choice of the practitioner

Article L.1110-8 of the Public Health Code recognizes the right of patients to freely choose their health professional and establishment as a fundamental principle of health-related legislation. In that sense, a ruling of the French Supreme Court [*Cour de cassation*] of 7 November 2000[39] has affirmed the right of a physician to sell his "clientele" provided that patients' free will would be preserved.
However, limitations are admitted on the basis of the technical capacities of the establishments, their rate base or the criteria governing the reimbursement of care. Furthermore, this right cannot ground the opposition to medical act on the basis of religious motives. In that sense, the obligation to designate an attending physician whose consultation is mandatory before any other consultation of other physicians, sanctioned by worse reimbursement rates, could limit the practical application of the principle of free choice.

6.3 Right to information

The Supreme Court [*Cour de Cassation*] links the obligation of information imposed to the healthcare professional to the constitutional principle of respect of human dignity.[40] The obligation of information appears as a fundamental right of the patient and an essential duty of the practitioner whose infraction could lead to liability. Article L.1111-2 recognizes the right of every person to be informed about his health condition fairly, clearly and in an appropriate manner. The information should be disclosed during a personal interview. In specific cases, e.g. for medical research, the information should be provided in written.
With regard to the content of the information to be provided, two cases should be distinguished:

- before the medical act, information should serve to the informed the consent of the patient and should bear upon the different investigations, acts or treatment proposed as well as their consequences, usual risks or known serious risks, as well as possible alternatives and their consequences in case of refusal.
- After the performance of the medical act, information should relate to new risks, e.g. the possibility of new undesirable effects of medicines.

Healthcare professionals are subject to this obligation in the limits of their competences. Three derogations to this obligation are foreseen. Firstly, when the patient cannot receive the information, because of his state of weakness, the legislator authorizes a "trustworthy person", previously designated by the patient, to be the recipient. Second, in case of emergency, i.e. a situation where a serious and imminent danger threats the life or the health of the patient, the health professional is not obliged to inform the patient. Finally, no information is required when the patient refuse to be informed about a diagnostic or prognostic, irrespective of its seriousness.

[39] Supreme Court, 1st Civil Chamber (Cass. Civ. 1ere), 7 nov. 2000, JCP G 2001, II, 10452, note F. Vialla.

[40] Supreme Court, 1st Civil Chamber (Cass. Civ. 1ère), 9 oct. 2001, n°00-14564, D. 2001, juris p. 3470, rapp. P. Sargos, note D.Thouvenin.

6.4 Right to access to the medical file

See section 5.3 above.

6.5 Right to consent to a medical act

Article L.1111-4 introduces for first time in a legislative text the principle of prior consent to the performance of medical acts or treatments. The healthcare professional that would perform the act or treatment without the prior consent of the patient would engage his liability. This right is absolute and is based on the principle of autonomy of the person implying that only the individual can decide upon the attempts to his body and on the principles of individual freedom and human dignity.

Specificities arise with regard to minors or protected majors. The consent of minors is required for acts relevant to their strict intimacy such as birth control or abortion. The Code moreover gives the right to the minor to keep secret his health condition and provides that his consent should systematically be sought whenever he is able to express himself and to participate to the decision. These two last cumulative conditions should be assessed against his capacity of judgment. The minor could however object to the consultation of his parents. The healthcare professional should in this case try to convince the minor, but if he maintains his opposition, has to perform the medical act. In any other case, the healthcare professional should obtain the consent of the minors' legal representatives.

Consent should be free and informed. When the refusal of the patient puts his life at risk, everything should be done to convince him to accept the necessary care. When the performance of the medical act seeks to protect life and health, the jurisprudence has recognized the right of the healthcare professional to perform the medical act despite the refusal of the patient (e.g. Jehovah witnesses). The Law of 22 April 2005 moreover recognizes the right for patients at the end of their life to decide to cease the treatment. The healthcare professional must respect this decision.

The consent of the patient can be kept in "anticipated directives" [*directives anticipées*] to be used by healthcare professionals for situations in which patients are not able to express their will. Articles R.1111-17 to R 1111.20 define the conditions of validity, confidentiality and storage. In case the patient did not draft "anticipated directives", the person appointed by the patient as "trustworthy" can take the decision in place of the patient. The trustworthy person cannot make a decision that would trigger serious consequences for the health of the minor or protected major.

6.6 Right to designate representatives

6.6.1 Representation of individual interests: the trustworthy person

Patients can designate a trustworthy person to be consulted in case they would not be able to express their will. This new right has been introduced by the Law of 4 March 2002 on the

basis of the proposition made by the National Consultative Committee of Ethics[41]. The designation has to be done in written and can appoint a relative, a close person or even the attending physician.
The trustworthy person is entitled to be consulted before any performance of medical acts, in a situation of emergency or when medical research is to be carried out. This person is granted with access to the medical information required for the decision except if the patient has objected to it. He can also accompany the patient and assist him during medical consultations.

6.6.2 Representation of collective interests.

The Law of the 4 March 2004 completed by the Law of 9 August 2004 and their application texts recognizes to health associations the right to defend the collective interests of users of the health system and to efficiently represent them. They participate in the definition of the health policy. They can also defend the interest of users' by exercising the rights recognized to parties in civil matters for infractions that can threat collective interests, and by participating to regional committees of conciliation and reparation, and to users' information organizations.

6.6.3 Obligation to pay the fees and of collaboration

Patients have the obligation to pay the fee due to the healthcare professionals. They also have the obligation to cooperate with the healthcare professional, meaning that they have to inform him of all the symptoms of their affection together with all relevant information required for the issuance of an accurate diagnostic. This obligation extends to personal and familial antecedents. Failure to provide such information would release the healthcare professional from his liability.
The patient should also follow the advices and prescriptions given by the healthcare professional. If not, the professional would be entitled to terminate the contract provided it does not trigger harmful consequences for the patient and for the continuity of the care.
The obligation of collaboration has been extended and since the deployment of public information campaigns, can be converted in an obligation to live a healthy life. In that sense, a smoker' heirs, who died from a lung cancer, were dismissed in their complaint against the national tobacco company because the judge considered that the smoker was the only one to make the decision to smoke, more when he knew the secondary effects via publicly available information.
Liability of patients is usually invoked as exemption for the liability of the healthcare professional (false declaration, negligence in following the treatment which compromises its effects). It can however not be invoked when the patient refuses to be operated on the basis of the inviolability of the human body. The Law of 4 March 2002 has moreover extended patients' collaboration obligation to their participation in ensuring the durability of the health system and of the principles it relies on. They are thus deemed to participate from the

[41] Comité Consultatif National d'Ethique, Opinion n°58 of 12 June 1998, Consentement éclairé et information des personnes qui se prêtent à des actes de soins et de recherché, available online at: www.ccne-ethique.fr

protection of their health following the recommendations issued by the authorities. Financial liability can be found in the scheme implemented by the law of public health policy of 2004 which reduces the reimbursement rates of the medical acts when the patient has consulted a healthcare professional without a prior prescription of his attending physician.

6.7 Rights and obligations of healthcare providers

Rights and obligations of healthcare providers have been adopted by the Medical Charter of 1927 and reaffirmed by the Medical code of ethics. Four main principles govern the practice of medicine: independence, freedom of prescription, free establishment and right to fee. This last right will not be further developed in this section as it represents little interest.

6.7.1 Principle of independence

Physicians cannot limit their professional independence in any way. This principle acts as a guarantee for the patient that the physician will act in his best interest and that he is not subject to a conflict of interests. It also means that the physician should remain independent towards the family of the patient.

6.7.2 Freedom of prescription

The freedom of prescription means that the healthcare professional is free in the choice of the medicine and treatment he prescribes according to his knowledge and conscience. However, this principle is not absolute and limits can be found in health economics, in the need to forbid useless or dangerous prescriptions, or the possibility for the pharmacist to replace a prescribed medicine for a generic one.

6.7.3 Free establishment

Any practitioner can open offices at any place without prior administrative authorization. Two derogations are admitted: the prohibition of installation in the a building where another health professional practices without his prior consent or the approval of the provincial council of the order of medicine; and the obligation to not re-establish at one place after a substitution of a certain duration.

7 Identity management in the health sector

A co-ordinated identity management system for the French healthcare sector including the identities of patients, healthcare professionals and other stakeholders is being developed via the use of identification cards by patients and healthcare professionals. The information in this chapter is based on our IDABC-report referenced under [RD9].

7.1 Overview

The French health network is based on two different smart cards meant to authenticate patients (Vitale Card) and professionals (Healthcare professional cards –*Carte de professionnel de santé*- the so-called CPS card). The CPS card contains a function of authentication and signature. The Vitale card contains only a function of authentication but a second generation of cards, more secure and technology-updated, is being issued since the beginning of 2007. It integrates a function of electronic signature, although not yet activated. More information is available at: www.sesam-vitale.fr for the Vitale card, and at: www.gip-cps.fr for the CPS card.
The VITALE card is delivered to any Social Security beneficiary older than 16 years and defines its rights to be reimbursed. It is based on the RNIAM number (National repertory inter-regimes of Health Insurance beneficiaries) generated from the national registration number (NIR, *numéro d'inscription au repertoire*).

The CPS is based on the personal number of the owner (ADELI/RPPS, FINESS and SIRET numbers). The CPS card is delivered by the GIP-CPS (authority of certification) to any healthcare provider (physician, dental surgeon, pharmacist) and to any professional led to deliver and to charge refundable services by the Health Insurance (e.g. : optician, sanitary haulage contractor). The identification bases on the personal identifier of the card holder (see infra). The CPS card also contains information relating to the structure of practicing, not for identification needs but for the GIP-CPS own management as well as for setting rates of services charged to he health Insurance.

7.2 Identification numbers

7.2.1 Identification of beneficiaries of social security: the NIR

Detailed information on the NIR can be found in section 5.5 of this report. The NIR is integrated to the RNIAM (Inter-regimes National Directory for beneficiaries of healthcare Insurance -*Répertoire national interrégimes des bénéficiaires de l'assurance maladie*) which is a national directory for the identification of beneficiaries of French Social Security. This directory serves as authenticated source of information for the identification of such beneficiaries. The RNIAM is used for the issuance of Vital Cards.

The RNIAM contains the data required for the registration of beneficiaries to Social Security. It does not contain either medical data or the address and professional or familial situation of the beneficiary..

7.2.2 Identification of healthcare professionals: from ADELI to RPPS

The inscription in ADELI [*Automatisation Des LIstes*] national register, relevant to the Health Ministry, is mandatory for health professionals prior starting their activity. It contains information on the civil status of the practitioner, its professional situation and the activities it has carried out in the past. The ADELI number is used as identifier within their relation with the Administration and it is used to issue the CPS cards and to authenticate these practitioners in the social security network.
In order to resolve insufficiencies of the ADELI directory, the main stakeholders involved in healthcare professionals identification issues agreed to define together a new organization aiming to develop sharing of information relating to health professionals, as well as for enhancing the reliability of the available data and efficiency of processes.
To that effect, it has been decided that the creation of a new directory, the RPPS (*Répertoire partagé des professionnels de santé :* health professionals shared directory) will replace the ADELI directory in 2009, while operational project ownership was delegated to the GIP-CPS.
The RPPS aims at setting up a tool of long-lasting and reliable identification of the health professionals, providing official reference on health professionals data for the use of any actor or institution having to handle information on their subject (authorization of practicing or setting-up, reimbursement management, follow-up of prescriptions, demography issues, forecast management of care supply, management of sanitary crises, phone books updating in the real-time, etc).
The implementation of the RPPS is linked to an institutional reform consisting first of all in delegating to the professional Orders, instead of services of the State, the charge of a main front office for all procedures (such as registration in the board, diploma recording, declaration of exploitation, regulating, demand of CPS card) the health professionals are obliged to prior starting as well as during their activity.

The directory will be mainly updated with the data sent by the Professional Orders. Firstly, its scope will be limited to Physicians, Dental surgeons, Midwives and Pharmacists. Its scope will be gradually broadened, including other actors from the health system (e.g. medicine students) as well as other health providers whose activity is regulated by the public health code.

In parallel, it is planned to optimize the processes of the creation and update of data production by involving other relevant institutions such as hospitals, universities, aiming at improving over quality / security / reliability of information issued by the directory.

A regulation act, issued after agreement of the CNIL, is expected to :

- describe the way of issuing RPPS data as reliable information ;

- allow the GIP-CPS to consult the RNIPP (*Répertoire national d'identification des personnes physiques :* national citizens identification directory) for certification of the data relating to registered professionals civil status (name, surname, birth-date & birth-place, …) ;
- define the RPPS data classification, especially as regards the public data scope and the users access rights relevant to their goals and functions.

7.2.3 Identification of legal persons : FINESS number

Registration in the FINESS[1] file is formally required for hospitals and for sanitary / social structures except liberal offices. This registration management is under responsibility of the Ministry of health ands leads to issuing FINESS number for use of :

- legal persons (according to meaning of SIRENE[1]) ;
- their geographical units.

These identifications enable to know when, for example, a health professional is practicing on his own or whithin a medical team in a hospital. They are required for allowing the health practitioner to access to the patient's medical file (as well for filling or consulting it), for following up medicine prescriptions and also for needs relating to pricing & payment of medical acts or performed services.
In the future, this file will be replaced by the RMESS[1] directory that will use SIREN (company id number) and SIRET (factory or unit id number) identifiers, issued by SIRENE register.

7.3 Identification cards

Created in 1996, SESAM-Vitale intended to computerised the healthcare system and to modernise, simplify and faster exchanges between the administration, the users and the healthcare professionals. The first step consisted of a claim forms' dematerialisation which have entailed the deployment of more than 60 millions of chip cards to the users (Vitale card) and 256,766 cards to healthcare professional (CPS card). However, it is not mandatory and the user can still use paper based claim forms.
The Vitale card is a personal card attributed to every beneficiary of French social security from 16 years on. Since 1996, the Healthcare Insurance agencies [*caisses d'assurance maladie*] have the obligation to deliver to every beneficiary an "electronic individual card", the so-called Vitale-card (Art. L.161-31 of Social Security Code).
The card has the dimensions of a bank card and allows its user to justify its reimbursements rights. It contains the NIR, name and surname of the owner and its beneficiaries, the social security regime, the competent administration in charge of his file and its reimbursement rights (Art. R.162-33—1 Social Security Code. This card should be updated at 'green access points' whenever the situation of the owner has changed.
Aiming at preventing fraud, the Vitale card 2 integrates a photograph of its owner on the printed face and in the chip. The chip could contain more information relative to the person

who to call in emergency cases, the holder's blood group, the name of their general doctor, details of their mutual company and their opinion on organ donation. It is being distributed since 2007. This is a smart card consistent with ISO 7816 standard with re-writable technology and a crypto-processor (Art. 1 of Ministerial Decree of 14 March 2007[42]). The chip contains two certificates, allowing the authentication of the card and its user. The user's certificate will permit to activate an electronic signature function (Art. 2). This card will be the key to the Electronic Health Records (DMP) and it is foreseen that this new card could be used as authentication means outside health sector.

The CPS cards contain mostly the same information except from the photograph (article R;161-52 of the Social Security Code and Ordinnance of 9 April 1998). The CPS card also contains information relating to the structure of practicing, not for identification needs but for the GIP-CPS own management as well as for setting rates of services charged to he Health Insurance via the DAM (= *Domaine de l'Assurance Maladie* : Health Insurance data set). The identifier used is not the NIR but the identification number of the owner (ADELI/RPPS, FINESS and/or SIRET number). This chip card contains two certificates, one to authenticate the user through a PIN code and the other with electronic signature functions.
The CPS card is delivered by the GIP-CPS (authority of certification) to any healthcare provider (physician, dental surgeon, pharmacist) and to any professional led to deliver and to charge refundable services by the Health Insurance (e.g. : optician, sanitary haulage contractor).

[42] Ministerial decree of 14 March 2007 relative to physical and logical features of health insurance card and to the data contained in this card [*relatif aux spécifications physiques et logiques de la carte d'assurance maladie et aux données contenues dans cette carte*], J.O of 17 March 2007

8 Electronic prescription

8.1 Framework applicable to medical prescriptions

Only the social security code has defined the obligatory information on medical prescription in the article R.161-45.
Article 79 of the Medical Code of Ethics limits the amount of information a prescription can contain to the following information: name, address, telephone number and fax, hours and days of consultation, qualification, diplomas and functions as recognised by the National Council of the Order; whether it practices alone or in a group; his situation towards health insurance agencies; qualification.
The physicians can prescribe all the cares, exams and drugs. As mentioned above, the monopole of prescription of physicians has moreover tended to be reduced. They now often share this prerogative with other healthcare professionals such as midwives, dental surgeons or nurses who can prescribe the cares or the drugs ordered by the law or decree.
As mentioned above, the freedom of prescription means that the healthcare professional is free in the choice of the prescription, of the acts according to his knowledge and conscience. However, this principle is not absolute and economical limits can be put by the identification of useless or dangerous prescriptions, or the possibility for the pharmacist to replace a prescribed medicine for a generic one. The healthcare provider who does not respect these measures to limit public expenses can be held liable economically.
Pharmacists should carry out a formal control of the prescription, meaning ensuring that the prescription is original and authentic and checking the identity of the healthcare professional who issued it whenever required. It should moreover check that the prescription is dated, signed and is still valid. This control raised the issue of the validity of prescriptions issued by physicians not established in France. The State Council recently changed its jurisprudence and ruled that the provisions of the Public Health Code governing the conditions required for the practice of medicine in France did not govern obligations of pharmacists who were thus not banned from delivering medicine on the basis of such prescriptions.[43]

Finally it is necessary to mention that some medicine, such as narcotics, requires the use of secured prescriptions. Secured prescription should be redacted on a white watermarked paper that indicate the name and address of the healthcare professional and the identification number of the prescription pack.

[43] State Council (CE), 27 févr. 2002, req. n° 227426, inédit, cité par E. Fouassier, Dispensation pharmaceutique : une intervention remarquée du Conseil d'État : Médecine et droit 2002, n° 57, p. 13

8.2 e-Prescription

8.2.1 E-PRESCRIPTIONS

For the first time, e-prescriptions have been introduced in the social security code in 1997 (article R.161-45 of the Social Security Code). Article 34 of the Law 2004-810 of 13 august 2004 on healthcare insurance has allowed the transmission of prescriptions of care and medicines by electronic mail provided that his author could be identified; the prescription was issued, transmitted and stored in conditions that guarantee its integrity and confidentiality; that a prior clinical examination of the patient had been carried out except in cases of emergency. The conditions required are listed in the decree n°2007-260 of 15 May 2007

The text does not however specify to whom the email should be addressed (patient, healthcare professionals, pharmacists, etc.). According to the Order of Medicine, an interpretation tending to acknowledged that the prescription should be addressed to the pharmacists should be preferred in order to prevent abuses.

The main problem thus resides in ensuring the confidentiality and integrity of the document, as well as the identification of the healthcare provider. The use of the health electronic cards, the CPS and the Vitale Card 2, which both integrate functions of electronic signature and authentication, could be used to overcome the problem of authenticity.

8.2.2 OTHER ELECTRONIC RECORDS

First of all, the healthcare insurance act of 13 august 2004 and the decree 2006-143 of 9 February 2006 have created a new database, the so-called “Web médecin” or “history of reimbursements”. The aim of the system is to allow doctors to consult the medical history of the patients they are treating by providing easy on-line access to information relating to the different medical interventions and or medicines that they have had reimbursed by social security over the past 12 months. The portal is managed by the National Health Insurance Fund for Employees (Caisse nationale d’assurance maladie des travailleurs salariés - CNAMTS) which controls access to the system and routes requests to the appropriate databases. The service is only accessible to physicians and only when they are delivering health services to the patient in question. Consultation of a patient’s history of reimbursements is subject to the patient’s prior agreement as it is accessed using the patient’s own health insurance card (Carte Vitale). Contrary to the DMP, the patient however does not have the possibility to mask information. After two years of experimentation, the CNIL has given on the 10 July 2007 the go-ahead for the wide-spread implementation of the ‘Web Medecin’ tool. [44]

[44] Epractice.eu, Press release, Web medecin goes national, www.epractice.eu/document/3996, 22 October 2007.

Second, a pharmaceutical record is foreseen to be deployed together with the DMP. The pharmaceutical record would allow pharmacists to share personal data about the delivery of medicines in order to prevent undesirable interactions. The records are hosted in a centralised database, accessible by every pharmacist, managed by a private provider, authorized by the CNIL. The creation of the pharmaceutical record is facultative and subject to the prior consent of the patient who can withdraw this consent at any time in the pharmacy of his choice. He can also object to the introduction of certain data. The pharmacist will access the records via the simultaneous introduction of his CPS and the Vitale card of the patient. They will be granted access only to the patient history of the last four months. It is moreover foreseen that the pharmaceutical records would be integrated into the DMP in the future.
The pharmaceutical records are currently under experimentation, financed by the Order of pharmacists. The CNIL has required the encryption of the records used for the experimentation. It should moreover be consulted prior to any generalisation about the feasibility and acceptability of the project.[45]

[45] CNIL, L'expérimentation du dossier pharmaceutique sur Internet va débuter, 25 May 2007, available online at: www.cnil.fr/index.php?id=2223

9 General assessment

The French regulatory framework has been recently adapted and prepared for the integration of eHealth applications such as ePrescription, electronic patient records or telemedicine into the healthcare system. This framework however still needs to be to developed and technical requirements needs to be defined in order to ensure a full deployment of the solutions it promotes. Some provisions moreover needs to be clarified and more precisely defined, as illustrated by the freeze of certification procedure for health data host providers because of the need of specific reference practices for security and interoperability which would ensure the interoperability of the systems used.

The full deployment of eHealth applications could however be slowed down by the low penetration rate of electronic means, as demonstrated by the relatively low levels of use of the Vitale Card and CPS by physicians for being in use for several years. An important factor for success is thus the management of the eHealth tools by the main stakeholders themselves. As pointed out by the National Committee of Ethics, the sole deployment of technical solutions will no be sufficient to solve more fundamental problems such as the collaboration of healthcare providers or to make patient aware of their responsibilities. To that effect, a great deal of hope is put on the successful implementation of the DMP which is expected to foster collaboration between healthcare professionals in the interest of patients and of the quality of care. Due to the significant delays taken by the project, several reports commissioned by the Parliament and the Government have established a situation picture of the state of the project, identifying the reasons for such delays, listing the remaining obstacles and offering a series of recommendations that should help for defining a new roadmap. Six principles have been identified by the GAGNEUX Report as to base the actions taken in that field: 1) the DMP should first be conceived as a tool for healthcare professionals, calling for the need to clarify the main concept of medical file, 2) technical choices should serve the needs of use in practice, 3) the content and the infrastructure should be evolving and a practical and experimental approach should be followed, 4) the roadmap should be flexible, realistic and readable, 5) the right balance should be found between security and friendliness of the system, 6) a coherent and efficient governance should be implemented for eHealth systems. As far as this last point is concerned, the Government has provided in the Law proposal for Finance and Social Security for 2009 for the creation of a new GIP, 'ADIP' (*Agence des Systèmes d'Information de santé Partagés*) in charge of the development of shared health information systems (new article L.161-36-4-3 of Social Security Code). This new agency will gather the functions actually devoted to the GIP DMP, the GIP CPS and the interoperability function of the GMSIH (GIP for Modernisation of Hospitals Information System - *pour la Modernisation du Système d'Information Hospitalier*). The GMSIH should morever be merged with the MAINH (Mission d'Appui à l'Investissement Hospitalier) and the MEAH (National Mission of Expertise and Hospital Audit - *Mission nationale d'Expertise et d'Audit Hospitaliers*) into a new agency named 'Agency for Hospital Efficiency' (Agence de l'Efficiencie Hospitalière). The creation of the GIP-ADIP is motivated by the need to have one single agency in charge of

developing shared e-health systems and control their infrastructure, in particular with regard to interoperability and security functions, as well as the modalities of deployment of the DMP. The Ministry moreover plans to create a National Council for eHealth systems (*Conseil National des Systèmes d'Information de Santé*) that will define a global strategy to ensure the consistency of health information systems.[46]

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

In general we expect that the development of reference practices for security and interoperability based on international standards specific to the health sector will be trigger for better coordinated and large-scale eHealth projects in various fields, including patients' summaries, telemedicine and electronic prescriptions. Experimentations are currently being carried out at local level.

From the perspective of cross-border interoperability, the approval of these reference practices of mandatory use by health provider for their platforms and related to e-administration reference practices should allow a greater interoperability of eHealth systems. The active part taken by SESAM vitale in the European project e-cardnet, a major actor of eIDM solutions in France, should go in the sense of the development of interoperable solutions not only at national but also at European level.

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30 November 2008

[46] Jean-Jacques Fraslin, L'ASIP cherche un budget et un chef, 4 Octobre 2008, http://www.i-med.fr/spip.php?article228#nb12

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