SMART 2007/0059

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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE BELGIUM

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European Commission
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1 Documents

1.1 Applicable Documents

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

1.2 Reference Documents

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

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

2 Glossary

2.1 Definitions

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

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

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

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

2.2 Acronyms

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

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OCSP ..... Online Certificate Status Protocol

PKI..... Public Key Infrastructure

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NRN..... National Register Number

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

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SSCD ..... Secure Signature Creation Device

SSIN..... Social Security Identification Number

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TTP ..... Trusted Third Party

3 Introduction

3.1 General overview of the Belgian healthcare system

A comprehensive and recently updated (2007) overview of the Belgian healthcare system can be found in the Belgian HiT country report published by the European Observatory on Health Systems and Policies (written by Dirk Corens)
http://www.euro.who.int/Document/E90059.pdf (194 p.).

From the executive summary of this report , we reproduce the following important observations:

"The Belgian health system is mainly organized on two levels, i.e. federal and regional. The federal Government is responsible for the regulating and financing of the compulsory health insurance; determining accreditation criteria; financing hospitals and so-called heavy medical care units; legislation covering different professional qualifications; and registration of pharmaceuticals and their price control. The regional governments are responsible for health promotion; maternity and child health services; different aspects of elderly care; the implementation of hospital accreditation standards; and the financing of hospital investment."

"The Belgian health system is primarily funded through social security contributions and taxation. Public sector funding as a percentage of total expenditure on health care fluctuates around 70%. The system is based on the principles of equal access and freedom of choice, with a Bismarckian-type of compulsory national health insurance, which covers the whole population and has a very broad benefits package. Compulsory health insurance is combined with a private system of health care delivery, based on independent medical practice, free choice of service provider and predominantly fee-for-service payment. All individuals entitled to health insurance must join or register with a sickness fund."

"Patients in Belgium participate in health care financing via co-payments, for which the patient pays a certain fixed amount of the cost of a service, with the third-party payer covering the balance of the amount; and via co-insurance, for which the patient pays a certain fixed proportion of the cost of a service and the third-party payer covers the remaining proportion. There are two systems of payment: (i) a reimbursement system, for which the patient pays the full costs of services and then obtains a refund for part of the expense from the sickness fund, which covers ambulatory care; and (ii) a third-party payer system, for which the sickness fund directly pays the provider while the patient only pays the coinsurance or co-payment, which covers inpatient care and pharmaceuticals."

"Most physicians – whether GPs or specialists – are paid on a fee-for-service basis. The patient pays the set fee for the consultation directly to the physician, and patients are then directly reimbursed by their sickness funds. Most services are reimbursed at a rate of 75%, so the patient shares 25% of the cost."

"The basic feature of Belgian hospital financing is its dual remuneration structure according to the type of services provided: services of accommodation (nursing units), emergency admission (accident and emergency services), and nursing activities in the surgical

department are financed via a fixed prospective budget system based on diagnosis-related groups (DRGs); while medical and medicotechnical services (consultations, laboratories, medical imaging and technical procedures) and paramedical activities (physiotherapy) are remunerated via a fee-for-service system to the service provider."
"Pharmaceuticals are exclusively distributed through community and hospital pharmacies. Only physicians and (to the extent that their profession requires) dentists and midwives can prescribe pharmaceuticals. About 2500 pharmaceutical products are on a positive list and therefore are partly or fully reimbursable. The reimbursable percentage of the cost varies depending on the therapeutic importance of the pharmaceutical."

3.2 Use of ICT in the Belgian healthcare sector

A recent (2007) status of the use of ICT by *general practitioners* in Belgium 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 Belgian country brief, we take over the following key findings:
"In terms of infrastructure, 86% of the Belgian GP practices use a computer, which puts the country on a par with its European neighbours. A similar situation can be found in relation to Internet connections: currently 84% of the Belgian GP practices have such a connection. In Belgium, broadband represents the most common form of access to the Internet with 80% of GP practices resorting to broadband connections. Electronic patient data storage is common in Belgium.
At least one type of individual data is stored in 84% of GP practices. Belgium scores slightly above the EU27 average use rates for all data types under observation.
A computer is available in the consultation room of 76% of the Belgian GP practices, it is actually used for consultation with the patients in 63% of the practices. 57% of the Belgian GP practices make use of Decision Support Systems either for diagnosis of prescription purposes (50% on average in the EU27).
In Belgium the electronic exchange of patient data via the Internet or other dedicated networks corresponds to European averages. The transfer of laboratory results in particular however is quite advanced: 73% of the GP practices use a network to receive results from laboratories. This is far more than the EU27 average of 40%. 13% of the Belgian GPs exchange data with other medical carers, a figure which stays close to the EU27 average. ePrescribing is used by 2% of GP practices in Belgium.
13% of the Belgian GPs use networks to exchange administrative patient data with other carers, as compared to the average rate of 10% attained across the EU27 Member States. With only 3% of the GP practices exchanging administrative patient data with reimbursers, Belgium scores far below the EU average of 15%."

3.3 National eHealth strategy

An overview of the Belgian eHealth policy can be found in the December 2006 ERA Report "eHealth strategy and implementation activities in Belgium" (Authors: Jos Devlies, Geert Thienpont, Georges De Moor): http://www.ehealth-era.org/database/database.html#belgium
For our Study, the following observations, adapted from this report, are important:
The Belgian strategy has traditionally based on incremental set of initiatives in order to remove, step by step, obstacles to the exhaustive use of eHealth services. Recent plans at the federal level have been: the introduction of the electronic identity card, the decision and the effective set-up of a eHealth backbone infrastructure, the registry of health professionals, the labelling of EHR systems for GP's, for dentists, for nurses and for physiotherapists etc…
These federal initiatives have been completed with regional initiatives as the legal framework for a future Health Information Network in Flanders, with the ambition to centralise all relevant data regarding health epidemiology and preventive care (a regional competence in Belgium).
The main efforts coordinated by the Ministry of Health have focused on the following aspects:

- Contributions via the "Telematics Commission" to the establishment of technical norms by recognised national experts. Since early 2000, the National Commission "Telematics Standards in relation to the Health Sector" have issued nine recommendations on the basic conditions for exchanging and sharing health information. Establish a certification process for minimum level of quality and interoperability of authorised ambulatory care software distributed on the Belgium market: https://portal.health.fgov.be/portal/page?_pageid=56,4280396&_dad=portal&_schema=PORTAL
- Adapt or develop key reference databases and codification systems for diagnostics, treatment, care and drugs: www.riziv.be
- Define an XML implementation for health related electronic messages, compatible with HL7: "Kmehr" (Kind Messages for Electronic Health Records): http://www.chu-charleroi.be/kmehr/htm/kmehr.htm
- Initiate health networks on a "loco-regional" basis (3 initiatives "Flow") to develop the concept of "shared health record": https://portal.health.fgov.be/portal/page?_pageid=56,4280426&_dad=portal&_schema=PORTAL

The primary objective of the Carenet project, launched in 2004, is to check insurance entitlement rights of patients and allow – when possible – third-party payment. It aims to establish a 99% paperless communication between insurance funds and all Belgian hospitals: www.carenet.be

Since 1998, all beneficiaries of the Belgian social security system use the SIS card. Certain health care providers such as pharmacists and all hospitals need to use a data access card in parallel (Security Access Module card): http://ksz-bcss.fgov.be/En/CBSS.htm
The SIS Card is also currently being used for other identification purposes, but is gradually being replaced by the Belgian eID card: http://eid.belgium.be
A law of December 2006 officially created a new government institution "BeHealth", unfortunately without further legal framework. The BeHealth portal is currently operational with a limited number of services and applications: www.behealth.be. One example of such an application is the web-based cancer registration (WBCR) by hospitals to the national cancer register.

Because a comprehensive legal framework for the exchange of health records was lacking at the federal level, separate legislative initiatives have been taken at the regional level. One illustrative example was the adoption, on 16 June 2006, of a decree establishing the Flemish "Health Information System" by the regional Parliament of Flanders: http://www.wvg.vlaanderen.be/juriwel/gezopreventie/prg/gis/decr160606.htm

The fragmented character of the Belgian policy in the area of eHealth will hopefully come to an end with the recent adoption of a new legal framework. This legal framework has been approved by the Belgian government on 20 March 2008, adopted by the Belgian federal Parliament before the summer and enacted on 21 August 2008 as the Law on the establishment and the organisation of **the eHealth-platform.**
In the following pages we provide a short overview of the new legal framework.
The eHealth Platform is a government institution, managed by representatives of several actors in the healthcare sector. It will create and manage a cooperation platform for secure electronic exchange of information about patients, provided care and the results of the provided care, and for the exchange of electronic care prescriptions between all relevant actors in the health care sector. Besides providing a network and basic services, it will also coordinate the development of functional and technical interoperability standards.
The eHealth Platform does not change the current division of tasks between the actors in the health care sector. It will not store information in a central way or monopolize electronic service delivery to the end users. It essentially provides basic services which can be used by providers of value added services. The platform makes use of the existing network infrastructure (internet, social security extranet, federal government network) with end-to-end encryption of the information (concept of virtual private network. The providers of value added services are also be able to use validated authentic data sources via the eHealth Platform but the administrators of these databases remain responsible for the availability and (the organization of) the quality of the information made available.
Obvious basic services provided by the eHealth Platform include:

- integrated user and access management;
- orchestration of electronic processes;

- portal environment including a content management system and a search engine (https://www.behealth.be);
- personal electronic mailbox for each health care provider;
- logging.

These services are completed by additional basic services that are currently being developed, in particular time stamping, coding and anonymizing and the provision of a reference directory. The reference directory indicates, on demand of the patient, which type of information with regard to the patient, the provided care and the results of the provided care is available at what places. It will, on the one hand, provide a table with fixed care relations between health care providers and their patients, the nature of the relation, the starting date and final date of the relation, and, on the other hand, a table indicating the places where, without a fixed care relation, electronic information is available about patients. It further has a multi-stage and decentralised character: a a general reference directory referring further to specific reference directories for each group of health care providers or each health care institution. The main functions of the reference directory are:

- preventive control on the legitimacy of the access to the information regarding a patient;
- routing of information requests to the places where the information about the patient is available;
- possibility of pushing automatically particular information to certain health care providers.

Authentication of the users of the eHealth Platform is adapted, according to the security level required and include the three traditional levels used in Belgian e-government services: the electronic identity card, a combination of user number, password and citizen token, or authentication by simple user number and password. Authentication will include verification of characteristics and mandates, necessary for accessing validated authentic sources and authorization to use an added value service managed by a service supplier. These authorizations are attributed on the basis of a generic policy enforcement model.
The eHealth Platform further makes use of currently existing validated authentic sources, such as the register of health care providers, held by the Ministry of Health and containing information about the diploma and the specialization of a health care provider identified through his social security identification number (SSIN). Other validated authentic sources are the database with recognitions of the National Institute for Sickness and Invalidity Insurance – which contains information about the social security recognition of health care providers identified through their SSIN -, and the database with the identities of the persons authorized to act on behalf of a health care institution, containing information about which persons, identified through their SSIN, are authorized to use which applications on behalf of a health care institution.
Among the first value added services provided via the eHealth Platform are the input into and consultation of the cancer register and the on line ordering of (paper) care prescription forms

(application called "Medattest"). Additional value added services are the electronic declaration of birth (eBirth) and the already existing network application for the exchange of data related to third party billing (sending third party billings electronically to sickness funds). Other services include in particular:

- entering the evaluation of disabled persons electronically into the information system of the Ministry of Social Security;
- support of electronic care prescription in hospitals;
- support of coding and anonymizing for RIZIV and sickness funds;

Some new added value services could be:

- electronic access by health care providers and health care institutions to the insurance status and other relevant administrative information regarding the patient;
- well co-ordinated, unique collection, across public services at several government levels and sickness funds, of information necessary for getting authorized to provide particular care;
- a standardized content, format and methods for legally valid electronic care prescriptions in the ambulatory sector;
- using the eHealth Platform as a trusted third party for coding and anonymizing health-related personal data with a view on further processing for research, historical or statistical purposes;
- gradually, making available in a decentralized manner and exchange standardized patient summaries.

Most insiders believe that the eHealth Platform will put an end to the fragmentation on the Belgian eHealth scene. The platform will be managed by the stakeholders in the healthcare sector themselves, be it in the framework of a government institution. It will offer basic services, such as identity management and data security, on the basis of which all kinds of public and private actors can easily plug in new value added services. Because the platform uses common procedures and standards, it will also lead to better interoperability, at least on a Belgian level.

3.4 Regulatory framework for patients' summaries

Belgium doesn't have legal provisions in the area of patients' summaries. It is planned to introduce the Summarized Electronic health Record (Sumehr). This is now already technically possible at the ambulatory care level (https://portal.health.fgov.be/portal/page?_pageid=56,4280424&_dad=portal&_schema=PORTAL)

3.5 Regulatory framework for telemedicine

There are no specific provisions in Belgium with regard to telemedicine. On the other hand, there doesn't seem to be major legal obstacles to practice telemedicine in Belgium. The scarce legal literature about telemedicine in Belgium refers mainly to the application of personal data protection law and shared medical secret and to the regulatory framework for information society services (transposition of the e-commerce directive). In order have a treatment reimbursed by the health insurance funds the physical presence of the physician seems to be required (Royal decree of 14 September 1984, art. 1 § 4bis on the nomenclature for medical treatments). It is not clear whether or not this requirement is entirely in line with EU Internal Market rules.

There is some jurisprudence in Belgium with regard to the liability of physicians who provided medical advice to patients by telephone but the rules applied are in line with the traditional liability for negligence (e.g. if a physician didn't have all relevant information about the patient's health because he was not physically present). Application of product liability rules may be relevant but the use of sophisticated technical devices is not necessarily more frequent in telemedicine than in the traditional hospital environment.

There has been a specific group working on telemedicine under the Telematics Commission which has produced a pre-recommendation. A new workgroup (SPF/RIZIV) is under preparation. The use of tele-radiology faces a specific limitation in Belgium due to the need to have ALL professionals involved duly registered.

3.6 Regulatory framework for electronic prescriptions

No specific legal framework exists for electronic prescriptions. On the other hand a e-Med (prescription) project has already gone quite far in proposing legal amendments (e.g. amending the Royal decree n°78, allowing electronic signature etc..) to allow electronic prescriptiosn intra-muros. For the ambulatory sector, a proposal is expected for the end of this year.

For most of the prescriptions, in particular for prescribing pharmaceuticals to the ambulatory patient, it is currently not possible to use electronic means to transmit a prescription. Electronic prescription is, on the other hand, possible in the hospital environment. For more details we refer to Chapter 8 of this report.

3.7 Overview of relevant legislation

Since the law of 21 August 2008 establishing the eHealth Platform entered into force, it is the most important legislative source in this domain. The main topics of the law relate to:

- the creation of the eHealth Platform as an organization, with an adequate legal basis determining its mission, its management committee and its user committee and their composition;
- the possibility to use a common patient identification number for all the basic and value added services which make use of the eHealth Platform;

- the attribution of probative value of electronic prescriptions, processes and information exchange;
- the management of the reference directory;
- effective methods for determining functional and technical interoperability standards;
- the required delegations for the adaptation of specific regulation in function of specific projects.

The formerly existing Be-health portal has its legal basis in article 4 of the law of 27 December 2006 "containing various provisions" but this the provision will be abrogated by the new law establishing the eHealth Platform (the term Be-health is abandoned because it refers only to the federal level, while the new eHealth Platform will serve federal as well as regional initiatives).

Further relevant legislative texts relate to the practice of health care, in particular the practice of medicine (Royal decree N° 78 of 10 November 1967, further cited as the Law on the Practice of Medicine). A new law on the liability for damages relating to health care provision has been enacted in 2007 but the entry into force has been postponed.

Of particular interest to eHealth are the laws on the protection of privacy in the contest of personal data protection (Law of 8 December 1992 on the protection of private life in the context of personal data processing) and the law on the rights of patients (Law of 22 August 2002 on the rights of patients). Specific legal texts regulate the management of medical records (see further).

Indirectly relevant are further the laws relating to social security (in particular the provisions relating to the social security information (SIS) card and the use of the social security identification number (SSIN), in particular the law of 15 January 1990 establishing the Crossroads Bank for Social Security). Data transmitted by electronic means by healthcare providers and health insurance organisations can be used as legal evidence ("except proof of the contrary") (Royal decree of 27 April 1999).

Also relevant are the laws with regard to the National Register (Law of and the use of the national identification number, the electronic identity card and the legislation with regard to electronic documents and electronic signatures (see Reference Documents under RD9 and RD10).

4 Regulatory framework for the healthcare profession

An overview of the regulatory framework for the medical profession in Belgium is presented in the Belgian monograph of the International Encyclopedia of Medical Law (author: Herman Nys): http://www.ielaws.com/medical.htm
This chapter of our report is largely based on this monograph.

4.1 Legal conditions for the practice of healthcare

The regulation of the education leading to the various professions in the healthcare sector in Belgium is a competence of the Communities (Flemish Community and French-speaking Community). The educational programs have been adapted to the European directives in this area. For the medical profession in particular, the Council Directives 86/457 on specific training in general medical practice and 93/16/EEC concerning the coordination of provisions in respect of activities of doctors, have influenced fundamentally education leading to general medical practice or medical specialization in Belgium.
The practice of medicine is regulated by Royal decree Nr. 78 of 10 November 1967 concerning the practice of the healing arts, nursing, allied health professions and medical boards. Healing arts comprise medicine, in which dentistry is included, when practiced on human beings, and pharmacy in both their curative and preventive aspects.
No person may practice medicine unless he holds a legal diploma of physician. This monopoly is exclusive, which means that with the exclusion of all others, physicians are competent to practice medicine. It is also all-embracing, which means that it covers every activity that has to be considered as belonging to medicine. An exception has been made for dentistry: generally speaking physicians are not allowed to practice dentistry. Another exception exists for midwives (to allow them to supervise childbirth, which is considered as a medical act).
To practice medicine in Belgium, the following requirements have to be fulfilled (for more details and for the requirements concerning other healthcare professions, see https://portal.health.fgov.be/portal/page?_pageid=56,512705&_dad=portal&_schema=PORTAL :

- Possession of the legally required diploma: diplomas awarded in other EU Member States are assimilated in accordance with the provisions of Council Directive 75/363.
- A visa from the provincial medical board competent for the place in which the physician intends to practice: nationals of other EU Member States may temporarily practice medical activities in Belgium, without having to fulfill the obligation of a visa (for example in case of emergency; a notification to the Ministry of Health is however required).
- Inscription on the list of the Order of Physicians: it is an offence for anyone to practice medicine without being inscribed on the list of the Order.

An act belongs to the field of medicine whenever it has the purported purpose, in respect of a human being:

- To examine the state of health;
- To detect diseases and disabilities;
- To establish a diagnosis;
- To introduce or administrate any treatment of a pathological condition;
- To carry out a vaccination;
- To supervise pregnancy and childbirth as well as any related procedure.

Preventive medicine belongs to the legal monopoly of physicians. Self-help or self-care is not considered as illegal practice of medicine (it is not an act *vis-à-vis* another human being). On the other hand the taking of blood samples is an act of medicine that may only be performed by physicians or nurses at the request of a physician. Radiographies are considered as purely technical procedures. Using appliances, for instance to measure blood pressure, heartbeat, pulsation, etc. is not considered as (illegal) practice of medicine in the context of self-examination or self-care. Whenever the appliance is used to examine the state of health of another human being, it can be considered as an act of medicine reserved to physicians.
There are divergent opinions on Belgium on the qualification as an act of medicine of certain activities, such as eye examination or the measuring of eye deviations, psychoanalysis and psychotherapy, group therapy. Providing written and oral advices and recommendations concerning diseases and their treatment, on the contrary, is not considered as an act of medicine.

4.2 Control over the practice of medicine

The practice of medicine in Belgium is supervised by the Order of Physicians. The Order includes all physicians who are permanently residing in Belgium and who are inscribed on the list of the provincial order where they have their permanent residence. Nationals of other EU Member States who are established as physicians in a Member State are entitled to provide medical services in Belgium without being registered on the list of the Order of Physicians in Belgium (but need to notify their activities to the Ministry of Health). 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 Belgian territory.
The most important function of the provincial councils of the Order of Physicians is to ensure observance of the rules of professional conduct for medical practitioners and the upholding of the reputation, standards of discretion, probity and dignity of the members of the Order.
The code of professional ethics, established by the Order of Physicians, contains the rules concerning the so-called continuity of care, medical secrecy, handing over of medical data to colleagues and the individual relations between a physician and this patients, colleagues, dentists, pharmacists and allied health professionals. The code further formulates the principles on the basis of which the social obligations of the physicians are determined and can further state which clauses are forbidden in agreements between physicians and other parties, when these clauses are not compatible to the principles of professional ethics and

more specifically to the therapeutic freedom of physicians. The King can give binding force to the code of professional ethics but has not used this competence up to now.

4.3 Professional liability

The law of 15 May 2007 (Moniteur, 6 July 2007) on the compensation of damage as a consequence of healthcare introduced the concept of faultless liability in the health sector. The basic principle of this law is that victims of damage as a consequence of healthcare do no longer have to proof the existence of a fault committed by the health professional. Normally the law had to enter into effect on the 1st of January 2008, but this date has been postponed. Many provisions of the law have been criticized and will probably be amended later this year. Consequently, the professional liability of a physician is, with the exception of disciplinary liability, currently not governed by special laws in Belgium. This means that both the civil liability and the criminal liability of the physician for damage or injury caused by improper performance of the duties entailed in the discharge of his professional functions, are governed by the general rules of civil and criminal law.

Civil liability of a physician arises when an obligation is not fulfilled. Obligations originate either from a contract or from tort. The Belgian courts have acknowledged the possibility of a contract for medical services existing between a physician and his patient or between the employer of a physician (a hospital) and a patient. Non-contractual or tortuous liability is only relevant in the case of damage to a third party or when services are rendered to a patient when the latter is not in a position to give consent to treatment.

It is not surprising that hospital physicians are more involved in malpractice actions than general practitioners, and, in general, physicians who practice outside the premises of a hospital. Many malpractice cases before courts relate to medical apparatus: actions based on the use of defective equipment, inexpert use of available apparatus and/or lack of supervision on the technicians using the apparatus. Especially anesthesiologists have been confronted with this sort of claims. A third category of malpractice suits relating to medical apparatus is based on the fact that no use was made of a piece of equipment, although it was available and in good shape at the time.

Characteristic of hospital medicine is that a patient is not confronted with one physician but with a medical team. This often complicates the determination of responsibilities when an accident happens. Matters are still complicated because a surgeon may employ their own nursing personnel while anesthesiologists can make use of personnel employed by the hospital. Also the physician may act under different statutes: as an employee, a civil servant or as a private service provider on his own account. The difference between these situations is directly relevant for the nature of the contractual relationship with the patient and consequently also for the discussion about liability for damages.

4.4 Professional secrecy

One of the most important legal obligations owed by a physician to a patient is the protection of confidences revealed by the patient to the physician. Article 458 of the Criminal Code lays

upon a physician a legal obligation not to disclose confidential information concerning a patient which he learns in the course of his professional practice.
The obligation of non-disclosure applies not only to information acquired directly from the patient, but also to information concerning the patient which the doctor learns from other sources.
The duty of medical secrecy is not limited to physicians who are providing healthcare to the patient. A physician who medically investigates a person at the request of an employer or an insurance company, is also bound by the duty, although he may inform in such a case the employer or the insurer within the limits of his mission.
Article 458 of the Criminal Code has a large field of application and not only applies to physicians alone but to everyone who, in the course of his professional practice, is being informed of confidential information. Therefore it is generally accepted that not only physicians but also nursing and paramedical personnel are bound to a duty of secrecy.
Because all the members of a medical team are obliged to respect the confidentiality of the patient's information, one accepts that this information may circulate within the team (so-called "shared medical secret").

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

Since 1992 Belgium has general legislation protecting the individual with regard to automatic processing of personal data. The law of 8 December 1992 has been amended in 1998 in order to transpose the provisions of the European Directive 95/46/EC.
Generally speaking the Belgian data protection law is very similar to the European directive. The Belgian legislator has been very reluctant to make a maximum use of his possibilities to specify or to further detail the provisions of the Directive. Therefore there is almost literal parallelism between the Belgian law and the Directive with regard to:

- the definitions of the essential concepts: personal data, processing, controller, processor, third party, recipient and consent (art. 2 of the Directive);
- the rules regarding data quality (art. 6 of the Directive) but, accordance with the Directive, the Belgian legislator has enacted detailed rules on the further processing of personal data for scientific, historical or statistical purposes;
- the criteria for making personal data processing legitimate (art. 7 of the Directive);
- the information to be given by the controller to the data subject (art. 10-11 of the Directive);
- the data subject's rights (art. 12, 14 and 15 of the Directive) although the Belgian legislation added a specific provision on access to health data (see further);
- the provisions with regard to confidentiality and security of processing (art. 16-17 of the Directive);
- the notification of the processing to the data protection supervisory authority (art. 18-19 of the Directive);
- the status and competences of the data protection supervisory authority (art. 20, 21, 22 and 28 of the Directive: more details about the Belgian Privacy Commission can be read at http://www.privacycommission.be.
- liability for damages as a result of unlawful processing (art. 23 of the Directive);
- transfer of personal data to third countries, outside the EU (art. 25-26 of the Directive).

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

As far as the processing of special categories of personal data is concerned (transposition of art. 8 of Directive 95/46/EC) the Belgian law contains separate provisions for a) sensitive personal data (= all data mentioned in art. 8.1 of the Directive except the data concerning health), b) data concerning health, and c) data concerning offences, criminal convictions or protective measures.

Art. 7 of the Belgian law regulates the processing of data concerning health and is formulated as follows:

"§ 1. The processing of health-related personal data shall be prohibited.

§ 2. The prohibition of processing data referred to in § 1 shall not apply in the following cases:

a. if the data subject has given his written consent to the processing of those data, on the understanding that the consent may be withdrawn by the data subject at any time; the King may lay down in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy, in which cases the prohibition of processing health-related data may not be lifted by the explicit consent of the data subject;
b. if processing is necessary for the purposes of carrying out the specific obligations and rights of the controller in the field of employment law;
c. if the processing is necessary for the realisation of an objective laid down by or by virtue of the law in view of the application of social security;
d. if processing is necessary for the promotion and protection of public health, including examination of the population;
e. if processing is made obligatory by or by virtue of a law, decree or ordinance for reasons of an important public interest;
f. if processing is necessary to protect the vital interests of the data subject or another person, provided that the data subject is physically or legally incapable of giving his consent;
g. if processing is necessary for the prevention of a concrete danger or the suppression of a specific criminal offence;
h. if processing relates to data that are apparently made public by the data subject;
i. if processing is necessary for the establishment, exercise or defence of legal claims;
j. if processing is necessary for the purposes of preventive medicine or medical diagnosis, the provision of care or treatment to the data subject or to one of his relatives, or the management of health-care services operating in the interest of the data subject, and if those data are processed under the supervision of a health professional;
k. if processing is necessary for scientific research and carried out under the conditions established by the King in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy.

§ 3. The King shall lay down in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy, the specific conditions with which the processing of personal data referred to in this Article, has to comply.

§ 4. Health-related personal data shall only be processed under the responsibility of a health professional, except for the written consent of the data subject or if the processing is necessary for the prevention of a concrete danger or for the suppression of a specific criminal offence.

The King may lay down in a decree agreed upon in the Council of Ministers after advice of the Commission for the protection of the privacy, which categories of persons are to be considered health professionals in the meaning of this law.

The health professional and his appointees or agents shall be obliged to secrecy with regard to the processing of personal data referred to in the first section.

§ 5. Health-related personal data shall be collected from the data subject.

They may solely be collected from other sources if this is in compliance with the paragraphs 3 and 4 of this Article and necessary for the purposes of the processing or if the data subject is incapable of procuring the data."

The following comments can be made with regard to art. 7 of the Belgian law:

- Personal data concerning health is not further defined. Belgian doctrine generally refers to the definition of the Council of Europe recommendations regarding the processing of health data: "The meaning of the term "personal data concerning health" (…) includes information concerning the past, present and future, physical or mental health of an individual. The information may refer to a person who is sick, healthy or deceased. This category of data also covers those relating to abuse of alcohol or the taking of drugs."

- Processing personal data concerning health on the basis of the consent of the data subject is only possible if the controller has obtained a written consent "writing" includes also electronic means used by the data subject to express his/her will.
- If processing is exclusively based on the written consent of the data subject, the controller has a larger duty to inform than usual. In addition to the normally requested information, he needs to inform the data subject about the reasons for the processing and also communicate him a list of the categories of persons who will have access rights to the data (art. 26 of the Royal decree of 13 February 2001).
- If processing is exclusively based on the written consent, the data subject should not be have a relationship of dependency vis-à-vis the controller, prohibiting him to freely give or refuse his consent. In such a case the consent would be considered invalid, unless the processing is clearly meant to benefit to the data subject (art. 27 of the Royal decree of 13 February 2001).

- Processing personal data concerning health is only lawful if it is done under the responsibility of a healthcare professional. The term "health professional" is not defined but according to the majority opinion in legal doctrine, the term not only refers to physicians but rather to a broad spectrum of healthcare professions.
- The data subject can provide a written consent for processing personal data concerning health without the supervision of a healthcare professional.
- When processing health-related personal data the controller has to keep a list of the categories of persons who can access the data and precise the reason why they need such access; this list should be kept available for the data protection commission.
- All persons who have access to the health-related data need to be subject to a legal or equivalent contractual duty of confidentiality with regard to the data concerned.
- As a matter of principle, personal data concerning health should always be collected directly from the patient. This rule has been taken over from the Council of Europe Recommendation

.

5.3 Information and access rights of data subjects

Art. 10, § 2 of the Belgian data protection law adds a specific provision on the right of the data subject to access personal data concerning his health.

" Any person shall have the right to get knowledge of the personal data that are processed relating to his health, either directly or with the assistance of a health professional.

Upon request of the controller or of the data subject, communication may be done through mediation of a health professional chosen by the data subject.

If there is apparently no risk of offending against the privacy of the data subject and if the data are not used for taking measures and decisions with regard to an individual data subject, communication may be postponed if the health-related data are processed for purposes of medical scientific research, yet only to the extent that communication would interfere seriously with the research and no later than the moment on which the research is terminated.

In that case the data subject must have given in advance his explicit consent to the controller that the personal data relating to him may be processed for purposes of medical scientific research and that communication of the personal data relating to him may be postponed for that reason."

5.4 Other relevant rules regarding personal data protection

Detailed provisions in the implementation Order of the Belgian data protection law regulate the further processing of personal data for research, historical or statistical 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 data extracted from government validated authentic sources. Validated authentic sources in this context are databases administered by government administrations, of which the use is obligatory for other government administrations, meaning that these administrations are not allowed to collect data directly from citizens and companies, if there already available in a validated authentic source. Typical validated authentic sources in Belgium are the National Register (containing minimal identification data of natural persons) or the databases of the social security institutions, made available through the Crossroads Bank for Social Security.

As a general rule, if a public or private entity wishes to make use of data stored in validated authentic sources, it will need a license from the data protection supervisory authority. To grant these licenses, a limited number of specialized independent sector-specific committees have been created. For example, the sector committee for the National Register will grant licenses to anybody who wants to access data from the Register or make use of the unique identification number allocated to every person registered.

Since March 2007 the sector committee for social security has been attributed an extension to its competence and is currently also competent for granting licenses with regard to health-related data. Such a license will be necessary for every entity wishing to use personal data that are processed via the future eHealth Platform.

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the law on the rights of patients of 22 August 2002. The description of this law in the following chapter has been adapted from the Belgian monograph of the International Encyclopedia of Medical Law (author: Herman Nys): www.ielaws.com

6.1 Scope of the law

Patient means" the natural person to whom healthcare services are provided, whether at his request or not". Healthcare means "the services that a health professional provides in order to promote, determine, preserve, restore or improve a patient's state of health or in order to support a dying patient." Following this definition, acts such as removing an organ from a donor, terminating a pregnancy, etc. do not constitute healthcare. Moreover medical experiments involving persons are not covered by the law's domain of application. Health professionals in the current state of the legislation are: physicians, dentists, midwives, pharmacists, physiotherapists, nurses, paramedics and nurse assistants. Practitioners of non-conventional medicine (Law of 29 April 1999) are also considered as health professionals.

6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is not further specified by the law. The only practical legal meaning would seem that a health professional who is sued by a patient, may seek a defense in the invocation of patient's non-co-operative behavior.

6.3 Right to quality care

High quality care, according to the explanatory report, entails care in accordance with the prevailing standards as determined by the current state of science.

6.4 Right to free choice

According to article 6 of the law, the patient has the right to freely choose his health professional and to change that choice, except for some restrictions in determined cases.

6.5 Rights related to information about the state of health

A patient has the right to receive from the health professional all relevant information necessary to assess his state of health and his prognosis. Communication with the patient must take place in clear language, adapted to the individual needs. The patient may request that the information be confirmed in writing. The obligation to inform the patient cannot be delegated by a physician to nursing or paramedical personnel. This doesn't mean that these latter categories of health professionals don't have a duty to inform the patient about the activities that they may legally perform.

Information is not provided to the patient if the latter explicitly requests not to know. The explicit request not to know can be given in writing or orally, in which case it has to be noted in the medical record.
It is accepted that a patient has a right to relinquish his right to information, but this relinquishing must be voluntary and certain. In this case the healthcare professional is no longer required to inform.
In exceptional cases the health professional may withhold information about the patient's state of health if disclosure would cause grave harm to the patient and on condition that the health professional has sought the opinion of another health professional (so-called "therapeutic exception").

6.6 Right to give consent

The patient has the right to consent well informed, freely and in advance to any service provided by a health professional. The consent is only valid for the medical intervention consented to. Consent must be given expressly, except when the health professional, after having adequately informed the patient, can reasonably infer consent from the patient's behavior; The consent has to be recorded and added to the medical record at the patient's or the professional's request and with the health professional's or patient's approval. The information to be given to the patient prior to the consent is specified in the law. Patients have the right to refuse or withdraw consent for any service.

6.7 Rights related to the patient's medical record

The patient has the right to a medical record, carefully updated and safely stored by the health professional. Every health professional should keep a medical record about every patient to whom he provides healthcare services.
Two Royal decrees of 3 May 1999 contain more detailed rules concerning the so-called General Medical Record (GMR) and concerning the medical records in hospitals.
The first decree of 3 May 1999 contains precise rules about the content of the GMR. There should be one GMR per patient, kept by the usual general practitioner. A patient can freely choose by which general practitioner his medical record should be kept and can modify this choice at any moment. He communicates his choice to his sickness fund, which forwards the number of patients per general practitioner to the Ministry of Health.
A medical record (not only the GMR) can be kept in paper or in electronic format. According to the code of professional ethics of the Order of Physicians it should be archived during 30 years.
The second decree of 3 May 1999 regulates the medical records to be kept by hospitals. Together with the nursing record, the medical record constitutes the "patient's record".
The decree explicitly states that the medical record can be kept in electronic format. It needs to be kept for at least 30 years in the hospital. The decree also contains precise rules with regard to the content of the medical record. Some of the documents in the medical record need to be signed by the physician(s) who provided care to the patient.

Hospitals should archive the records of all patients who left the service, preferably in a central database or at least per service and in electronic format with a unique number per patient. The archive should be accessible to physicians who are involved in the provision of care to the patient.
Patients have the right to access their own medical records. A patient's request to access his medical record shall be granted as soon as possible and not later than 15 days following the request. The health professional's personal notes and information relating to third parties are excluded from the right of access to medical records. Personal notes are limited to notes which are never accessible to others, not even to the other members of a medical care team.
Patients have a right to obtain a copy of their medical records, in whole or in part, at cost price, as soon as possible and not later than 15 days following the request. Again personal notes and information relating to third parties are excluded. Each copy shall clearly indicate that it is strictly personal and confidential. A health professional can refuse to supply a copy if there are clear signs that the patient has been pressured to ask a copy of his medical record at the instigation of a third party.
The law determines, finally, also the conditions under which the next of kin may consult the deceased patient's medical record.
A Royal decree of 21 September 2004 regulates the patient's record to be held by homes for elderly care, rest homes or centers for daycare.

6.8 Right to protection of privacy and intimacy

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health. They have also a right to the protection of their intimacy. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to assist in the provision of care, without the patient's consent.

6.9 Right to representation in case of incompetence

The law contains rules to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient will be involved in exercising his rights, bearing in mind his age and level of maturity. Minor patients who are deemed capable of reasonably grasping their situation may exercise their rights on their own behalf.

7 Identity management in the health sector

A co-ordinated identity management system for the Belgian healthcare sector including the identities of patients, healthcare professionals and other stakeholders is not yet available. There is however a trend to use the general Belgian eIDM system (based on a combination of the National Register, the Crossroads Bank for Social Security and the electronic identity card), developed during recent years for public government services, also in the healthcare sector. The information in this chapter is based on our IDABC-report referenced under [RD9].

7.1 Overview

The prevalent eIDM system in Belgium is based on the Belgian Personal Identity Card, a mandatory electronic identity card that is intended to facilitate access to eGovernment services for all Belgian citizens from the age of 12 and up, as well as offering access to a variety of other services. Detailed information is available through the official Belgian eID website (http://eid.belgium.be; available in Dutch, English and French). The card contains a chip holding two certificates: one for authentication purposes, and one for qualified signatures.

The system is closely linked to the Belgian National Register (*Rijksregister/Régistre national*), which contains a key set of authentic attributes for certain citizens registered in it. Many of the attributes stored in the authentication certificate of the eID card are obtained directly from the National Register.

The eID card is linked to the National Register through the National Register number, which functions as a unique identifier for Belgian citizens in eGovernment services. Apart from being the main access key to the National Register, this number is also included as a serial number on the certificates of the eID card.

Alternative tokens include the paper federal token which can be issued to certain residents of Belgium (typically because they have not yet been issued an eID card), the social security card (SIS-card), private sector issued certificates (either software certificates or smart card based), and the recently introduced kids-ID, an eID card intended for children under 12.

Alternative identifiers include the identity card number and the social security number (SSIN).

Identification information with regard to legal persons is primarily stored in the so called Crossroads Bank for Enterprises, which identifies legal persons (and natural persons – entrepreneurs) by the so called enterprise number.

7.2 The SIS Card

Prior to the introduction of the national eID card, roll-out of the so called Social security Information System (SIS) Card was concluded in 1998. The SIS card is a smart card with a bank card format, similar to the generic eID card but without a photo of the bearer. It is mandatory, and the card is issued by any insurance fund to any person subject to the Belgian

health care regime, starting at birth (i.e. including employees, the self employed, unemployed, children, public officials) and regardless of nationality.
The following information is printed visibly on the card: the national register number, last name and two first names, date of birth, gender, SIS card number, and expiry date of the card. The chip on the card contains the same information, as well as the health insurance fund (by identification number of the fund and of the holder within this fund) and medical benefit information (i.e. social insurance status (e.g. employee, self employed,…) which determines the refund rate for specific medication.
The card is used by health professionals, specifically by hospitals, doctors and pharmacists, to verify the public medical insurance status (i.e., it contains administrative data, but not actual health information). This requires a specific reader[1], which is only issued to mandated persons and organisations. The card is not secured with a specific PIN-code, since the information can only be read through those readers.

7.3 Crossroads Bank for Social Security

The Crossroads Bank for Social Security (CBSS: http://www.ksz.fgov.be/En/CBSS.htm) was created 15 years ago as a way of improving the efficiency of Belgian social security organisations and to streamline services to the affected users. The key notion to understand is that this crossroad bank is not an official register in the strict sense (i.e. a container of attributes for a specific set of entities). Rather, the crossroad bank holds a reference directory in the form of a relational database, which can refer to the authentic source for any given piece of data, but which does not contain any data about the subjects itself. Thus, it minimises data redundancy (by retaining only one authentic source for any information) and improves efficiency (since this information can be located directly through the crossroads bank).
By automating information transfers between decentralised service providers, this goal could be achieved without impairing privacy by collecting all information in a gigantic central database. Information exchanges between the databases of social security organisations are strictly regulated, and are only possible after obtaining an appropriate mandate to do so by law[2], or by the sector committee of social security, a committee within the Belgian Privacy Commission[3].
As a practical necessity of the Crossroads bank, the so called ‘Bisregister of the Crossroads bank of social security’ was created, as an alternative database for anyone who is not entered in the National Register, but who is none the less subject to Belgian social security regulations. This alternative database contains a minimal identification dataset, consisting of the Crossroads bank number, first and last name(s), place and date of birth, gender, nationality, official address and invoicing address, place and date of death, and marital status.

[1] For specifications, see http://ksz-bcss.fgov.be/nl/documentation/document_3.htm

[2] Specifically the Law of 15 January 1990 establishing and organising a Crossroads Bank of social security. See http://www.juridat.be/cgi_loi/loi_a.pl?language=nl&caller=list&cn=2000102040&la=n&fromtab=wet&sql=dt='wet'&tri=dd+as+rank&rech=1&numero=1

[3] See http://www.privacycommission.be/machtigingen/Sociale_zekerheid.htm

The information is first registered when one becomes subject to Belgian social security by the entity who is personally confronted with the new subject, and is thereafter kept up to date by the institutions of the social security. As a consequence, all persons in the Bisregister can also take advantage of social security services, even if they are not entered in the National Register.

7.4 Patient identifier

As noted above, identification of the citizen is primarily based on his national registry number. Use of this number is strictly monitored, and subject to prior approval by a sector committee within the Privacy Commission (http//www.privacy.fgov.be). This same number is also used within the Crossroads Bank for Social Security (http://ksz-bcss.fgov.be) to exchange social security personal data between administrations. Similarly, companies and organisations are also assigned a unique identification number to be used in conjunction with the so-called Crossroads Bank for Enterprises (which also incorporates the central trade registry and the national registry of legal persons).
The law establishing the eHealth Platform states that the eHealth Platform is authorized to have access to the National Register and to use the National Register Number (NRN). For all exchanges to and from the eHealth Platform physical persons are identified by means of their National Register Number or – if they are not registered in the National Register – by their Social Security Identification Number (SSIN).
The obligatory use of the NRN of SSIN is restricted to data exchange via the eHealth Platform. As far as personal data are exchanged via other channels (for example directly from one hospital to another or via private network services), the actors in the healthcare sector are free to use other identifiers. If they wish to use the NRN for such transmission or access identification data of persons who are not in the National Register but registered by the Crossroad Bank for Social Security, they will need the usual license of the competent sector committee established in the framework of the Belgian Privacy Commission.

7.5 Authentication of healthcare professionals

Healthcare professionals are registered in the federal register (so-called “Cadaster”) of healthcare professionals, established by the Ministry of Health. This register contains information about the diploma and the specialization of a health care provider identified through his social security identification number (SSIN)
https://portal.health.fgov.be/portal/page?_pageid=56,585303&_dad=portal&_schema=PORTAL
The Cadaster is not yet available online but will be used as a so-called validated authentic source by the eHealth Platform to verify authorizations with regard to medical records and other data or applications. Other validated authentic sources which will be used in this context are the database with recognitions of healthcare providers, held by the National Institute for Sickness and Invalidity Insurance (RIZIV), also identified by their SSIN and the database with persons authorized to act on behalf of a health care institutions (e.g. hospitals).

Healthcare professionals (but also patients and other actors in the healthcare sector) are able to access data and applications on the eHealth Platform after authentication by means of their electronic identity card, a combination of user number, password and "citizen token" or a simple combination of user number and password alone. The precise means of authentication will depend on the required security level of the solicited application. Authorizations to use added value services provided by suppliers, other than the eHealth Platform itself, are managed by those service suppliers.

7.6 Exchange of health-related data

From a technical-organisational perspective, the eHealth Platform has an important role in the creation and the management of a so-called Reference Directory. Such a directory is successfully being used since many years in the context of the Crossroads Bank for Social Security.
Basically such a Reference Directory contains the following information:

- It indicates, on demand of the user, which type of information with regard to the patient, the provided care and the results of the provided care is available where. The reference directory thus doesn't contain the medical information itself (only references).
- It contains, on the one hand, a table with fixed care relations between health care providers and their patients, the nature of the relation, the starting date and final date of the relation.
- It contains, on the other hand, a table indicating the database where, without a fixed care relation, electronic information is available about patients.

It is possible that the Reference Directory of the eHealth Platform will end up in a multi-stage and decentralised implementation: a general reference directory that refers to specific reference directories for each group of health care providers or each health care institution.
The Reference Directory has essentially three main functions:

- preventive control on the legitimacy of the access to the information regarding a patient;
- routing of information requests to the places where the information about the patient is available;
- possibility of automatic communication of information to certain health care providers.

From a legal perspective, every transmission of health-related data through the eHealth Platform will require an authorization from the sector committee for social security and health, established in the framework of the Belgian Privacy Commission. An exemption from the obligation to apply for such an authorization will be the healthcare professionals who need

to access the data of a patient they are personally taking care of for diagnosis, prevention or treatment.

8 Electronic prescription

Article 21 of the Law on the Practice of Medicine determines that any prescription needs to be signed and dated by the physician or by the dentist and that it should indicate, as far as possible, the way the medicine should be used.
Besides this general provision, prescriptions are regulated by a complex web of regulatory texts which have been enacted in the framework of the health insurance.
In Belgium a distinction is being made between seven categories of prescriptions:

- kinesiology, nursing, bandages, orthopaedics, opticians, etc.
- medical imaging;
- clinical biology;
- pharmaceuticals;
- prostheses;
- dietetics;
- speech therapy.

Every prescription should contain a minimal set of data but the format of the prescription document is only obligatory for pharmaceutical prescriptions in the ambulant context (not for prescriptions in a hospital environment). In all other case healthcare providers can theoretically transmit prescriptions by electronic means and secure them by means of advanced electronic signatures (e.g. using the electronic identity card).
A Royal decree of 8 June 1994 establishes the model of the prescription document for the delivery of pharmaceutical products needed by patients who are not hospitalized. It is formulated as follows:
Art. 1, § 1: Except for patients who are hospitalized or who receive pharmaceuticals in a hospital in a context of ambulatory care, the pharmaceutical treatments, mentioned in article 34, 5° of the consolidated law of 14 July 1994 concerning the obligatory insurance for medical care and reimbursements, should be prescribed on the document "pharmaceuticals prescription" of which the model is joined in annex 1.
§ 2. The prescription for pharmaceuticals should be printed on white paper and the name and surname of the prescriber, as well as his identification number at the National Institute for Health and Invalidity Insurance, should be printed in figures and in a barcode. The prescription should be 20 cm long and 10.5 cm large.
§ 3. The prescriber should entirely fill out the prescription and put his stamp in the dedicated field where his name, surname and address are mentioned. "

The content of the prescription is for each category regulated in the so-called "nomenclature" and regularly updated. The nomenclature determines for every item the amount paid by the social security

A patient is free to take the prescription to the healthcare provider of his own choice. It is forbidden for a physician to mention the name of the provider on a prescription (art. 142, § 1, 7° of the consolidated law of 14 July 1994). The physician should write, manually or by means of a computer, the prescription himself (by his own hand") (art. 127 of the law of 14 July 1994).

For prescriptions with regard to clinical biology, the law explicitly specifies that the analyses can be prescribed by electronic means, if the applied method guarantees the identity, the approval and the authenticity of the prescription.

9 General assessment

With the enactment of the law of 21 August on the establishment and the organisation of the eHealth-platform, the Belgian regulatory framework is now ready for a full implementation of eHealth projects such as the exchange of patient's summaries, telemedicine or electronic.
In the following months things will change rapidly because the health sector will be able to fall back on the existing infrastructure for identity management in the public sector, making use of the National Register, the Crossroads Bank for Social Security and the electronic identity card. An important factor for success is the management of the eHealth platform by the main stakeholders themselves.
For the development of cross-border eHealth services, the Belgian legal landscape contains no specific peculiarities. The transposition of the European data protection directive into Belgian 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 creation of the eHealth Platform will be trigger for better coordinated and large-scale eHealth projects in various fields, including patients' summaries, telemedicine and electronic prescriptions. The development of such projects will probably lead to the adaptation of the legal framework for these projects.
From the perspective of cross-border interoperability, the connection of the health sector to the identity management system used for public government services, will logically lead to the adoption of similar solutions in that area as well. The solution which will ultimately be chosen to make public government services interoperable on a EU level, will automatically also be valid in the domain of eHealth.

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