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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE DENMARK

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1 Documents

1. Applicable Documents

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

2. Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 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 infections, whether directed to individuals or to populations.
- **Health professional**: a doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on

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 Danish healthcare system

A comprehensive and recently updated (2007) overview of the Danish healthcare system can be found in the Danish HiT country report published by the European Observatory on Health Systems and Policies (written by Martin Strandberg-Larsen, Mikkel Bernt Nielsen, Signild Vallgårda, Allan Krasnik and Karsten Vrangbæk)
http://www.euro.who.int/Document/E91190.pdf (187 p.).
From the abstract of this report we reproduce the following general characterization:

"The Danish health care sector is dominated by the public sector and is financed by local and state
taxes. Somatic and psychiatric health care, carried out at public hospitals, and primary health services, which are delivered by general practitioners (GPs) and other practising health professionals, are administered by the regions. The regions are financed by the State and to a certain extent by the municipalities. The regions own and run most hospitals, and practising health professionals are self-employed and reimbursed by the regions, mainly using a fee-for service mechanism. The municipalities are responsible for elderly care, social psychiatry, prevention and health promotion, rehabilitation and other types of care that are not directly related to hospital inpatient care. Access to health care is fairly equal when health status is taken into account. For all citizens with residence permits, access to health care is free of charge at hospitals and from GPs, whereas access to pharmaceuticals, dentists and some other services require co-payment. During recent years, the focus of health care reforms has been on patient choice, waiting times, quality assurance and coordination of care. A major structural reform in 2007 has changed the political and administrative landscape of health care, dramatically reducing the number of regional and local units and transferring health care responsibilities for prevention and rehabilitation from the regional to the local level."

From the executive summary of this report we reproduce the following important observations:
"The Danish health system is governed by a combination of national state institutions, regions and municipalities. All three levels have democratically elected assemblies and there is a tradition of decentralization of management and planning to the regions and municipalities. National-level institutions include the Parliament, the Government and various state bureaucratic institutions. The state level is responsible for the overall legal framework for health care and for coordinating and supervising the regional and municipal delivery of services. Five regions are responsible for delivering both primary and secondary health services. Most hospitals are owned and operated by the regions, and hospital doctors are salaried employees of the regions. Practising doctors are private rather than state practitioners, but receive almost all of their income from services paid by the regions."

"Like the other Scandinavian countries, Denmark is characterized by a strong welfare state tradition, with universal coverage of health services mainly financed via taxation. Access to the health system, including diagnostic and treatment services, is free for all citizens except for certain services such as dental care, physiotherapy and medicine requiring patient co-payment. Equity and solidarity are important underlying values in the system, and surveys show a persistently high level of patient satisfaction."
"Since 2007, financing has been obtained through earmarked proportional taxation at the national level. Most of this revenue (80 %) is redistributed to the regions via block grants, based on objective criteria (social and demographic indicators) and 20 % is redistributed to the new municipalities which will use these funds to co-finance regional hospital services for their respective populations."
"Doctors' fees are negotiated with the public authorities on a regular basis and activity profiles are monitored regularly. GP gatekeeping has been a significant feature of the Danish system for many years, along with the general principle of treating patients at the lowest effective care levels opposed to providing free access to more specialized units".

3.2 Use of ICT in the Danish healthcare sector

Since the beginning of the 1990'ies it has been a central goal to promote the use of ICT in the Danish healthcare sector. This strategy has been very successful in regards to GP's and less successful in the hospital sector. An external review report from 2007 regarding the use of electronic health records concludes that too many actors have been involved in the implementation of the national eHealth strategy and that centralized management at a national level have been lacking: Deloitte, "Strategiske udviklingsveje for epj. Eksternt review af det hidtige epj-arbejde, 27. april 2007" (Deloitte, "Strategic development of electronic health records. External review of the previous work regarding electronic health records", 27 April 2007): http://www.sum.dk/artikler_sum_dk/Files/Fil1/4256.pdf (only in Danish)).
In general, ICT is widely used among GP's. A recent (2007) status of the use of ICT by GP's in Denmark 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 Danish country brief, we take over the following key findings:

"Denmark is one of the frontrunners — mostly the top performer — of ICT use among General Practictioners in the European Union. This concerns both the availability of ICT infrastructure (computer, Internet) and the use of ICT for different eHealth-related purposes.

In terms of infrastructure, 99% of the Danish GP practices use a computer. The same share of practices disposes of an Internet connection. In Denmark, broadband represents the usual form of access to the Internet with 91% of GP practices resorting to broadband connections.

In contrast to most other European countries, Denmark scores well with regard to all aspects of eHealth use covered by the survey. This relates to the local use of a computer for consultations and data storage as well as to the networked transmission of patient data. With regard to the availability of a computer in the consultation room as compared to the actual use of the PC in consultations with the patients, there is nearly no gap as both availability and use are nearly universal (98% of practices and 92% of practices respectively).

Local Electronic Health Records are common practice in Denmark. Medical patient data is stored in digital form in more than 90% of GP practices. This means that Denmark shows results that are well above the EU27 averages with respect to the storage of all types of patient data. Especially remarkable is the high share of stored radiological data which in Denmark is the reality in 98% of the GP practices. This stands in stark contrast to the average storage rate of radiological data, which is at 34% in the EU27.

In Denmark the use of electronic networks for the Transmission of medical patient data is well established and widespread. 96% of GP practices receive analytic results from labs and 74% exchange data with other health care providers. In both cases Denmark holds the top position vastly above the EU27 average exchange rates for medical data. As far as ePrescribing is concerned, Denmark is one of only three EU member states where ePrescriptions are extensively used. Also with regard to this point, Denmark holds top a position as 97% of GP practices reported the regular utilisation of ePrescribing.

One reason for the frontrunner position currently held by Denmark in the eHealth domain may be the Danish history of dedicated eHealth strategies that ranges back to 1996. The development of Electronic Patient Records (EHR) in particular has been launched already in 1996. The most recent eHealth strategy that was conceived in 2003 provides for the comprehensive implementation and the further upgrading of EHRs. Plans are made for the extension of the ePrescribing system to arrive at a personal medication profile stored on a national prescription server and 29 individual initiatives in the eHealth domain have been agreed on."

3.3 National eHealth strategy

The Danish Ministry of Health has launched a number of eHealth strategies since mid-1990'ies:

- "Strategy for the development of Electronic Patient Records", 1996;
- "National Strategy for Information Technology in Hospitals", 1999;
- "National Strategy for Information Technology in the Healthcare System 2003-2007", 2003 http://www.sst.dk/publ/Publ2004/National_IT_strategy.pdf ;

- "National Strategy for Digitalisation in the Healthcare System 2008-2012 – for the Promotion of Public Health, Prevention and Care", 2008. http://www.sdsd.dk/~/media/Files/Strategy_english.ashx

The initiatives taken to implement the strategies include:

- Development of the Danish Health Data Network;
- Development of EDI standards for communication both for administrative and health care purposes;
- Development of common standards, concepts and classifications to ensure good integration between EHR's and other electronic systems in the health care sector;
- Development of communication system between hospitals and home care services;
- Development of a national Personal Medicine Profile;
- Development of a Prescription Server;

A brief overview of the Danish initiatives can be found in the Database of European eHealth priorities and strategies (Empirica), http://www.ehealth-era.org/database/database.html (country profiles) [RD 4].

It is characteristic for the Danish eHealth strategy and the implementation hereof that despite of the strategic focus, specific initiatives have developed bit by bit and with a number of different actors involved. In some areas there has been extensive progress; e.g. use of ICT among GP's. In other areas there have been immense challenges, and the development has been less successful; e.g. use of EHR in the hospital sector. In general, a vast number of IT systems has been developed and are actually operating in the health care sector. This offers a challenge in terms of ensuring sufficient integration.

One of the most important actors has been MedCom, which is collaboration between public authorities, organisations and private firms. The aim of MedCom has been the development and quality assurance of electronic communication and information in the healthcare sector, and MedCom has involved in a number of the above listed initiatives. Further information about MedCom can be found at the website http://medcom.dk/default.asp?id=110014.The National Board of Health (Sundhedsstyrelsen: www.sst.dk)has also been involved, especially in regards to initiatives relating to the development of a consistent clinical terminology.

In 2003 the national eHealth Platform – sundhed.dk – was launched:www.sundhed.dk . It provides a single access point to both citizens and health care providers. The Platform offers general disease-specific information as well as directory services, information on waiting time etc. Furthermore, using their digital signature, citizens have access to a number of services, e.g. access to medical data, renewal of prescriptions and communication with healthcare providers and authorities. Health care professionals can also use a special digital signature to get access to patient data, laboratory results and electronic resources such as clinical guidelines (see further in chapter 7)

As mentioned in chapter 3.2 the "National Strategy for Information Technology in the Healthcare System 2003-2007" was reviewed in 2007. The review report concludes that too many actors have been involved in the implementation of the national eHealth strategy and

that centralized management at a national level have been lacking, see Deloitte: "Strategiske udviklingsveje for epj. Eksternt review af det hidtige epj-arbejde, 27. april 2007" (Deloitte, "Strategic development of electronic health records. External review of the previous work regarding electronic health records", 27 April 2007). http://www.sum.dk/artikler_sum_dk/Files/Fil1/4256.pdf (only in Danish)). As a result of the review report's recommendation a new organisational structure was established between the public stakeholders involved in eHealth; that is the Ministry of Health and Prevention, The National Board of Health, the Association of Danish Regions, Local Government Denmark, the Danish Medicines Agency, Sundhed.dk and Medcom. The new organisation - Coherent Digital Health in Denmark (Sammenhængende Digital Sundhed i Danmark) – was established in 2007: http://www.sdsd.dk/ In the new national eHealth Strategy the general focus is on three issues: To support quality and efficiency in health care, to create better services to and better inclusion of citizens and patients, and to establish more coherence through stronger collaboration ("National Strategy for Digitalisation in the Healthcare System 2008-2012 – for the Promotion of Public Health, Prevention and Care", 2008.). The strategy stipulates a step by step approach where smaller and more limited projects are followed by more complicated projects. The strategy is further elaborated in four action plans, and the proposed initiatives include a national patient index, a national medicine card, access for citizens to patient index and to booking and consent services, development of a common IT architecture and development of technical and procedural standards. The action plans are available in Danish from the website http://www.sdsd.dk/ .

There is no special or comprehensive regulatory framework developed as a response to the eHealth strategies. In general, rules and regulations regarding the relation between the patient and the health care provider and regarding protection of privacy and processing of personal data are also operating in areas affected by the use of eHealth technologies and services. Neither the Ministry of Health nor the Parliament has expressed a need for the development of a legal framework specifically designed to address issues in eHealth care. However, a number of legal initiatives have proven to be necessary in order to pave the way for or to further regulate the use of eHealth. The most important initiatives are the following:

- Separate rules in the Health Act (consolidated act nr. 95 from 7. February 2008) regarding access for health care professionals to patient information stored in electronic medical records or registers. The rules are described in more details in chapter 5.2;
- Separate rules in the Health Act regarding access to the Personal Medicine Profile. The rules are described in more details in chapter 5.2;
- Separate rules in the Consolidation Act on Legal Protection and Administration in Social Matters 2007 (lovbekendgørelse nr. 1047 af 27. august om retssikkerhed og administration på det sociale område) regarding automatic electronic exchange of information between the hospitals and home care services. The Act is available in English at http://eng.social.dk/index.aspx?id=713a4d80-2c8a-4421-8784-35c02009a3ce According to section 12c of the Act municipal authorities and hospitals

may for the purpose of preparing care tasks etc. exchange information about admission of citizens in the municipality to hospitals and discharge from them. The exchange can med made automatically and without the citizens consent,

Until now it seems that the law has been changed in situations where legal provisions were considered to be an impediment for technological progress and promotion of eHealth. However this approach might be under change. In the latest national eHealth Strategy it is specifically stated that data security and patient privacy is of concern and that it is necessary to investigate how technological solutions may be used to ensure compliance with the legislation. Such an analysis is most welcomed and hopefully the coherence established at the organisational level in regards to eHealth management may influence on the position taken towards the relation between law and technology in this area.

3.4 Regulatory framework for patients' summaries

One of the focal points in the latest eHealth strategy is on the development of a Danish National Patient Index which is intended to be a single, comprehensive electronic patient record for each individual citizen. According to the plan of action it is planned to make an analysis regarding the possibility of producing a patient summary on the basis of the patient's personal patient index. http://www.sdsd.dk/~/media/Files/handlingsplannotat.ashx (only in Danish). As regard the regulatory framework, there are no special legal provisions in the area of patients' summaries.

3.5 Regulatory framework for telemedicine

Telemedicine is not widely used in Danish. However, there have been some initiatives – especially in the Funen area – which is reported in a Medcom-report from 2006 ("Telemedicine in practical application" http://medcom.dk/default.asp?id=110014). The Danish National Board of Health has issued legal guidelines regarding liability and other legal matters in connection with physicians' use of telemedicine ("Vejledning nr. 9719 af 9. November 2005 om ansvarsforholdene m.v. ved lægers brug af telemedicine" https://www.retsinformation.dk/Forms/R0710.aspx?id=10132 (only in Danish)). The guidelines refer to rules and principles in the existing legislation which also applies in connection with use of telemedicine, and the guidelines concludes that the use of telemedicine does not affect the usual legal liability and other legal obligations of physicians. There is only scarce legal literature about telemedicine. A legal assessment of the use of Telemedicine can be found in the technology assessment report "Telemedicinsk præhospital diagnostic af akutte hjertepatienter. Et nyt IT-baseret concept" ("Telemedicine as a diagnostic tool in regards to emergency coronary patients. A new IT-based concept") http://www.sst.dk/Applikationer/cemtv/publikationer/docs/Telemedicin/ren.htm (only in Danish). There is no jurisprudence with regard to the liability of physicians using telemedicine.

3.6 Regulatory framework for electronic prescriptions

Electronic prescriptions are widely used in Denmark. In the European Pilot Study on eHealth indicators 'Benchmarking ICT use among General Practitioners in Europe" (Empirica) it is reported that 97 % of Danish GP's are using ePriscriptions.
http://ec.europa.eu/information_society/eeurope/i2010/benchmarking/index_en.htm
As regard the regulatory framework there is no specific legal regulation regarding electronic prescriptions, but electronic prescriptions are addressed in the general administrative regulation on prescriptions. For more details we refer to Chapter 8 of this report.

3.7 Overview of relevant legislation

A number of Danish Acts and regulatory instruments affect the use of eHealth in the Danish Health Care Sector. The most important are the following:

- Health Act (consolidated act nr. 95 from 7. februar 2008)
- Act on Authorization of Health Care Professionals and of Provison of Health Care 2006 (lov nr. 451 of 22 maj 2006 om autorisation af sundhedspersoner og som sundhedsfaglig virksomhed);
- Act on the Right to Complain and Receive Compensation within the Health Service 2005 (lov nr. 247 af 24. juni 2005 om klage- og erstatningsadgang i sundhedsvæsenet);
- Act on Processing of Personal Data 2000 (lov nr. 429 of 31 maj 2000 om behandling af personoplysninger)
- Administrative Order on Prescreptions 2007 (bekendtgørelse nr. 155 af 20. februar 2007 om receptor)
- Guidelines Regarding Liability and other Legal Matters in Connection with Physicians' Use of Telemedicine 2005 (vejledning nr. 9719 of 9 November 2005 om ansvarsforholdene m.v. ved lægers brug af telemedicine)

Also relevant are the laws with regard to the National Register and legislation with regard to electronic documents and electronic signatures (see Reference Documents under RD9 and RD10).

4 Regulatory framework for the healthcare profession

4.1 Legal conditions for the practice of healthcare

In Denmark practice of medicine is not an exclusive monopoly of physicians or other health care professionals. However, a number of treatments and practices are reserved for health care professionals who have obtained a legal diploma authorizing him or her to practice a particular profession. In addition, persons without a legal diploma can be punished if they treat people who are ill and thereby expose them to discernible danger. Furthermore, only health care professionals with a legal diploma are allowed to entitle themselves as "physician", "nurse" etc.

Persons who have the required educational skills and who have affirmed to the physicians' oath are entitled to have a legal diploma of physician. Nationals of other EU Member States with an EU primary medical qualification or citizens of a country with an agreement of free movement of persons (EU-doctors) are covered by Council directive 93/16/EEC (as amended) concerning the promotion of the
free movement of doctors and mutual recognition of their certificates, diplomas and other evidence of formal qualifications in medicine.

The regulation of the education leading to the various professions in the healthcare sector in Denmark is a competence of the Ministry of Science, Technology and Innovation (Ministeriet for Videnskab, Teknologi og Udvikling) together with the National Board of Health, the Ministry of Health and Prevention and a number of advisory boards.

The practice of medicine is regulated by Act on Authorization of Health Care Professionals and of Provision of Health Care 2006 (lov nr. 451 af 22 maj 2006 om autorisation af sundhedspersoner og om sundhedsfaglig virksomhed). The practice of pharmacists' is regulated by Consolidating Act of Pharmacies 2007 (lovbekendtgørelse nr. 657 af 28 juli 2007 om apoteksvirksomhed). The legal diploma confers both rights and duties to the professionals. The duties include a general obligation to practice good care and a number of more specific obligations e.g. to report information to the National Board of Health and to various medical and administrative databases. The rights relate to the use of title and to the monopoly provided for the health care professionals.

The monopoly conferred to physicians with a legal diploma is both positively and negatively delimited in law. Section 74 of the Act on Authorization of Health Care Professionals and of Provision of Health Care stipulates that only physicians with a legal diploma are entitled to treat infectious diseases, to perform surgery and obstetrics, use anesthetics and use pharmaceuticals which must be prescribed. Some exceptions are made in regards to dentists and midwifes, and the physician may use assistants and authorize them to perform some of the medical practices which are under their monopoly. In addition the monopoly could be delimited negatively from section 73 which stipulates that persons without a legal diploma are – within the limit of section 74 – free to provide treatment and care to persons who are ill, provided that the do not expose the patient to any discernible danger.

The Act on Authorization of Health Care Professionals and of Provision of Health Care does not clarify precisely which acts belong to the field of medicine and there have been discussions about the legal monopoly in connection with e.g. acupuncture, piercing and cosmetic services. Section 74 of the Act on Authorization of Health Care Professionals and of Provision of Health Care now clearly stipulates that use of needle acupuncture – which is defined as "surgery" – fall outside the legal monopoly of physicians'.

4.2 Control over the practice of medicine

There is a comprehensive system of control and supervision of health care professionals in Denmark. The Act of Authorization of Health Care Professionals and of Provision of Health Care contains the general provisions regarding professional conduct and duties including the obligation to provide *good care*. The Act furthermore stipulates the sanctions available for the National Board of Health in cases of misconduct. In addition, the Act on the Right to Complain and Receive Compensation within the Health Service 2005 (lov nr. 547 af 24 juni 2005 om klage og erstatning inden for sundhedsvæsenet) regulate the functioning of the Patients Complaints Board which is a disciplinary board assessing cases of malpractice and violation of patients rights. The Patients' Complaints Board is an impartial public authority, and the decisions from the Board serve to establish whether a health care professional is guilty of malpractice. Information about the Patients Complaints Board is available on www.pkn.dk. The Board may express its criticism of the health care professionals and may also submit serious cases to the public prosecutor, but the Board is not entitled to impose sanctions on health care professionals. However, The National Board of Health is automatically informed about decisions from the Patients Complaints Board and these decisions serve as the legal basis for the sanctions available for The National Board of Health. These include orders regarding future practice and – in cases of serious misconduct – also partial or complete deprivation of the legal diploma. A list of health care professionals who have received serious criticism from the Patients' Complaints Board or have been sanctioned by The National Board of Health is publicly available on the web (http://www.sundhed.dk/wps/portal/_s.155/4504?_FOLDER_ID_=1023051115134209)
The regulatory framework covers all physicians with a legal diploma who are practicing medicine in Denmark.
The Danish Medical Association has issued a code of ethics and a number of ethical guidelines (http://www.laeger.dk/portal/page/portal/LAEGERDK/LAEGER_DK/LAEGEFAGLIGT/RET_OG_ETIK/ETIK). Physicians who do not comply with these rules may be sanctioned internally by the ethical councils set up by the association. However, the ethical rules do not have a formal legal position in regards to the above mentioned Acts. The ethical codes of the medical professions do not specifically address eHealth.

4.3 Professional liability

Inspired by the Swedish system, a no-fault compensation system was introduced in Denmark in 1992. The basic principle of this system is that victims of damages in the health care

system do not have to proof the existence of a fault committed by the health care professional to be compensated.
The Act on Right to Complain and Receive Compensation in Health Service 2005 stipulates the criteria for providing compensation. In brief there are four criteria:

- *specialist criteria*. If it is assumed that an experienced specialist in the field in question would in the given circumstances have acted differently during examination or treatment, thereby avoiding the injury
- *apparatus defect criteria.* If the injury is due to malfunction or failure of technical apparatus, instruments or other equipment
- *retrospective criteria.* If on the basis of the evaluation, the injury might have been avoided using another available treatment that would have been just as effective from a medical point of view
- *fairness criteria.* If injuries are more extensive thatn the patient should reasonably have to endure given the severity of the injury, the patients illness and general state of health, the unusualness of the injury and the general possibility of taking the risk of its occurrence into consideration

The patient insurance scheme is operated by a private company – Patientforsikringen (Patient Insurance Association). See further information on http://uk.patientforsikringen.dk
If a health care professional is responsible of severe or repeating misconduct it might be possible to establish criminal liability which is also a possibility in cases of violation of the penal code.

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. Section 152b of the Criminal Code (lovbekendtgørelse nr. 1260 af 23 oktober 2007, Straffeloven) lays upon a physician and other health care professional with a legal diploma a legal obligation not to disclose confidential information concerning a patient which he learns in the course of his professional practice. The same obligation applies to those who assist the physician in the provision of treatment and care (section 152c). Furthermore, all public employees are also under an obligation of secrecy (section 152), which is important as most health care is provided by the public health care sector.
The obligation of non-disclosure applies to all kind of confidential information and not only to medical data and it covers both information acquired directly from the patient, as well as information concerning the patient which the doctor learns from other sources.
The Health Act (consolidated act nr. 95 from 7. februar 2008) contains more detailed provisions regarding the disclosure of confidential information about patients to other health care professionals in connection with treatment and care (article 41-43) as well as to other persons, authorities, institutions and companies (article 44-49). In general, the obligation of

secrecy also applies between different health care professionals, and patient's consent is – as a point of departure – needed whenever confidential information is shared with other health care professionals. However, in a number of situations the Act allows for disclosure and exchange of confidential information based on either presumed consent or an assessment of vital public or private interests (see in more details in chapter 5.2). Disclosure of information to persons and institutions outside the health care sector is regulated by a more strict privacy regime, and the patient's written consent is as a main rule necessary. However, there are exemptions from the obligation in cases where there is a legal obligation to disclose information or where substantial interests of other persons or of society speak in favor of disclosure. Special legal rules apply in the area of biomedical research, employment and insurance.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

General legislation on protection of the individual with regard to automatic processing of personal data was introduced in Denmark in 1978 with two separate acts for the private and the public sector. The legislation was substantially revised in year 2000 in order to implement the European Directive 95/46/EC.

Generally speaking, the Act on Processing of Personal Data (lov nr. 429 af 31 maj 2000) follows the structure of the European directive. However, there are a few special rules reflecting national standards, and the Act must be seen in context with other Acts containing provisions regarding processing of personal data – e.g. the Health Act. In section 2 the Act stipulates as a general rule that any rules on processing of personal data in other legislation which give the data subject a better legal protection takes precedence over the rules laid down in the Act. Compared to the Directive there is parallelism 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, in accordance with the Directive, the Danish 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); however, the Danish legislator has added a special provision regarding so called "purely private data", which includes data about criminal offences and serious social problems. According to the directive these data are not considered to be sensitive, but in the Danish act stricter rules apply to these data than to other (non-sensitive) data;
- 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). However, there are more detailed rules regarding patients rights to access to medical information in the Health Act;
- 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 Danish Data Protection Agency (Datatilsynet) can be read at http://www.datatilsynet.dk
- 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 Danish Act on Processing of Personal Data is also quite similar to the wording of the directive. However, there are special provisions in other Acts which supplement the Act on Processing of Personal Data. This includes the processing of confidential personal data in the health care sector which is regulated in the Health Act and the Act on Authorization of Health Care Professionals and of Provision of Healthcare.

There is no precise definition of "health data" in Danish law. However, in the travaux prépératoire to the Act on Patients Rights it is stipulated that the term "health data" covers information about the diseases, the patient's state of health and contact to the health care sector. This definition is also applicable in regards to the Health Act.

In regards to health information the Act on Processing of Personal Data stipulates as follows in section 7:

"7. - (1) No processing may take place of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, or data concerning health or sex life.

(2) The provision laid down in subsection (1) shall not apply where:

1. the data subject has given his explicit consent to the processing of such data; or
2. processing is necessary to protect the vital interests of the data subject or of another person where the person concerned is physically or legally incapable of giving his consent; or
3. the processing relates to data which have been made public by the data subject; or
4. the processing is necessary for the establishment, exercise or defence of legal claims.

(3) (…)

(4) (…)

(5) The provision laid down in subsection (1) shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under law to the obligation of professional secrecy."

This provision is – in practice – substituted by special provisions in the Health Act. According to section 40 of the Health Act it is a patient's right that health care professionals observe secrecy concerning confidential patient information he learns in the course of his professional practice. Based on this "manifesto" the Act stipulates in further details the rules regarding disclosure and collection of confidential medical data. The Act distinguishes between disclosure of health information to other health care professionals in connection with treatment and care (section 41-42), collection of electronic medical data in connection with treatment and care (section 42a, 42b and 42c) and disclosure of health information for other purposes (section 43-45). There are special rules concerning disclosure of health information for scientific and statistical purposes (section 46-48) and disclosure to third countries (section 49). Furthermore, there are special rules concerning the Personal Medicine Profile in section 157. The focus will primarily be on section 41, section 42a and section 157 as these are the most interesting provisions in regards to eHealth.
In general, disclosure is allowed if the patient has given his or her explicit consent. However, dependent of the situation, there are a number of exemptions. Section 41 is concerned with disclosure of information to other health care professionals in connection with treatment and care and the wording of the provisions is as follows (authors translation):
§ 41. With the patient's consent health care professionals may disclose information to other health care professionals about the health, other purely private matters and other confidential information regarding the patient, in connection with the provisions of treatment and care of the patient concerned or other patients.
Stk. 2 Disclosure of the aforementioned information is allowed without the patient's consent provided

1) it is necessary in connection with the current treatment of the patient and it is in the patient's best interest:
2) disclosure consist of a discharge letter from a hospital physician to the patient's General Practitioner or to the specialist who has referred the patient to hospital treatment;
3) disclosure consist of a discharge letter from a physician at a private hospital or clinic to the doctors mentioned in 2), if treatment is performed in accordance with an agreement under the act:
4) disclosure is necessary due to substantial public interests or of a significant interest of the patient, including a patient who can not defend his or her own interests, the health care professional or others;
5) information is transferred to the patient's General Practitioner from a substituting physician.

Stk. 3. The patient is entitled to object to disclosure of information based on sub-section 2.1-3.
Stk. 4. The health care professional who control confidential information is entitled to decide whether disclosure of information is justified

Stk. 5. If information is disclosed under sub-section 4) the patient must as soon as possible be informed about the disclosure and the purpose of disclosure, unless this can be omitted according to other legislation or for public or private interests protected by this Act.
The following comment can be made in regards to section 41 of the Health Act:

- As a mail rule the patient's consent is necessary in connection with disclosure to other health care professionals. An oral consent is sufficient (see section 42).
- The purpose of section 41, subsection 2.1 is to ensure that information which is necessary in connection with current treatment and care may be communicated to other health care professionals involved in the actual treatment of the patient. Disclosure is based on the patient's presumed consent, and according to section 41, subsection 3, the patient is entitled to veto the communication. The other derogations from the consent requirement in section 41 are primarily concerned with the GP's interest in obtaining relevant health related information about his or her patients.
- Compared to article 8 of Directive 95/46/EC and to section 7 of the Danish Act on Processing of Personal Data, this provision specify when processing is necessary for the purpose of medical practice and it may also provide the patient with a stronger privacy protection, as the patient's consent seem to be necessary in situations where this is not required by the Directive. Furthermore, the patient has a right to object to disclosure which exceeds the right to object according to article 14 of the Directive.

The provisions regarding professional secrecy and disclosure of information in the Health Act origin from the Act on Patients' Rights which came into force in 1998. At that time there were no widespread use of electronic medical records in the hospital sector, and the provisions regarding medical files in the Act on Patients' Rights were designed to function in a non-electronic information environment. Later it came into view that the wording of the provisions was not suitable in an electronic information environment where health care professionals are provided with direct access to electronic medical records and databases. As a reaction, the Health Act was amended in 2007 with section 42a-c. These provisions are explicitly dealing with collection of electronic medical data.
The following comment can be made in regards to section 42a of the Act on Health:

- Compared to section 41, section 42a provides physicians and hospital dentists with more extensive access to patient information. Sub-section 42a stipulates that if necessary physicians and hospital dentists are entitled to access electronic medical files to obtain information regarding the patient's health and other purely private and confidential matters. It is required that the accessed information is "necessary" in connection with "current care" and the physician may consequently access a medical record with extensive information about the patient to select the information which is relevant in connection with the provision of care.
- Other health care professionals have more limited access to electronic information. Access for this group is restricted to electronic systems which only contains information about patients who are receiving treatment at the particular unit where the

health care professional is working, and they are only allowed to access information regarding the current treatment which is necessary to provide proper treatment and care (section 42a, sub-section 2-3).

- As is the case in regards to section 41, this section 42a is based on the patient's presumed consent, and patients are entitled to oppose access to his or her electronic medical information (section 42a, sub-section 7). However, if sufficiently substantial interest speaks in favor of allowing access it is possible to overrule the patient's objection (section 42a, sub-section 5).

Section 157 of the Act on Health is concerned with access to the patient's Personal Medicine Profile. The Personal Medicine Profile is a register which provide an electronic overview of the purchase of prescribed pharmaceuticals. All purchases are registered automatically on the citizens' individual personal profile. Registration is mandatory. The following comments can be made to this provision:

- According to section 157, physicians are entitled to have access to the Personal Medicine Profile of patients who are currently receiving treatment, provided it is necessary to the actual treatment and care. A physician may also access the Personal Medicine Profile to investigate if his or her patients are being treated inappropriately with pharmaceuticals. Compared to section 41 and 42a of the Act, the patient does not have a right to object in regards to access to the Personal Medicine Profile.
- Nurses and social assistants are under certain circumstances also entitled to access a patient's Personal Medicine Profile, provided the patient has given an oral or written consent.
- Pharmacist may access the Personal Medicine Profile with the patient's oral or written consent or if it is necessary for the deliverance of pharmaceuticals to the patient.
- It should be noted, that the Data Protection Agency raised its concern during the public hearing regarding the draft proposal for the Personal Medicine Profile, see "Datatilsynets Årsberetning 2002", 2003, p. 25-29 ("Annual Report of Danish Data Protection Agency 2002", 2003, p. 25-29) http://www.datatilsynet.dk/fileadmin/user_upload/dokumenter/AArsberetninger/aars_02.pdf (only in Danish))

5.3 Information and access rights of data subjects

According to section 31 of the Danish Act on Processing of Personal Data, data subjects are entitled to have access to personal information which has been processed. The provision also covers access to health information. However, the Act on Health has separate rules regarding access to health information which substitute section 31 of the Act on Processing of Personal Data. Section 37-38 of the Health Act stipulates (author's translation):

"**§ 37.** Where a patient submits a request to that effect, the patient shall be informed whether or not data relating to his or her health in patients records etc are being processed. Where such data are being processed, communication on the patient's request shall take place in an intelligible form about;

1. the data that are being processed;
2. the purpose of processing;
3. the categories of recipients; and
4. any available information as to the source of such data

(2) The right to access according to sub-section 1 may be delimited in so far as the patient's interest in obtaining this information is found to be overridden by essential considerations for the patient himself or for other private interests.

§ 38. Decisions regarding the right of access must be taken by the public authority, institution or health care professional who posses the patient record etc.

(2) The public authority, institution or health care professional shall reply to a request without a delay and decide about whether access should be provided in form of a copy or by having an opportunity to inspect the patient record etc
(3) If the request has not been replied to within 10 days from the receipt of the request, the public authority, institution or health care professional shall inform the patient on the grounds for this and of the time at which the decision can be expected to be available.
(4) In situations where according to sub-section 1-3 a health care professional is entitled to make a decision regarding the patients right of access, the overall legal responsibility is on the operationally responsible authority"

The rules regarding access to medical records in the Health Act only covers health information which has been collected in connection with the provision of care. If health information has been collected for other purposes – e.g. for scientific purposes – the rules in the Act on Processing of Personal Data are applicable. In general, the data subject does not have right to access information which has been collected for scientific purposes, see section 32, sub-section 4 of the Act on Processing of Personal Data.

5.4 Other relevant rules regarding personal data protection

Further use of health information for administrative purposes is an important issue. Health data are both used for health administrative purposes and for other administrative functions, such as social security issues. In general, Danish legislation is quit liberal in regards to disclosure of health data for administrative purposes. Health care professionals are under a legal obligation to report various data to centralized data bases, and in regards to other public authorities it is normal administrative routine that public authorities should give each other a helping hand. In general, the data controller has the authority to assess whether disclosure of information is justified according to either the Act on Processing of Personal Data or the Health Act.
Another area of concern is the patient's right to have information in health records corrected or deleted. In general, patients do not have a right to have incorrect information deleted from

their records. If health information is incorrect, it must be noted in the patient's record, and the correct information must be stored, but it is forbidden to delete incorrect information.

6 Rights and duties of healthcare providers and patients

The rights' of patients and duties of health care provides are primarily regulated in the Health Act of June 2005. A comprehensive description of patients rights in Denmark is provided in the Danish country report produced by EuroGentest 2007 (authors: Herman Nys et. al.): www.eurogentest.org

6.1 Scope of the law

The definition of a "patient" in Danish law is equivalent to the definition used by WHO, that is "User(s) of health care services, whether healthy or sick", (WHO, "A Declaration on the Promotion of Patients' Rights in Europe", 1994). According to section 5 of the Health Act the term "patient treatment" encompasses examination, diagnostics, treatment and care, midwifery, rehabilitation, prevention and health promoting measures. Removal of an organ and termination of pregnancies without medical justification is not covered by this definition. However, the Health Act has special rules regarding both organ donation and abortion. The Act does not cover medical experimentation and assisted procreation where special acts apply. Health professionals in the current state of the legislation are defined as authorized health professional; that is those with a legal diploma, and assisting personnel operating under the responsibility of an authorized health care professional. Pharmacists are covered by special legislation which is also the case in regards to psychologists. Practitioners of non-conventional medicine are not considered as health professionals except in cases where they have a legal diploma or perform their activities under the responsibility of an authorized health care professional.

6.2 Duty of the patient to co-operate

The duty of the patient to co-operate is not further specified by the law. If the patient does cooperate it might, however, have implication for the provision of treatment and care. Thus, a non co-operating patient may be seen as a non-consenting patient. Furthermore, GP's are entitled to be released from his or her duty of care towards a patient who is unwilling to co-operate.

6.3 Right to quality care

According to section 2 the Health Act aims at providing treatment of high quality.

6.4 Right to free choice

There are different dimensions of the right to free choice. In "negative" terms this express the requirement that patients must give a voluntary and informed consent to treatment. Compulsory treatment is only allowed in special situations of psychiatric care. In "positive" terms free choice refers to the patient's right to choose between various kind of treatment, health care professionals etc.

According to section 16 of the Health Act patients has a right to receive information regarding his state of health, the available options for treatment the risks of complications and side-effects associated with the treatment. Communication with the patient must take place in a respectful form and information must be adjusted to the patient's individual capability. The obligation to inform the patient can be delegated by the physician to another health care professional, but the responsibility to provide proper information remains at the physician. Information shall be given orally and may be supplemented by written information. Patients right not-to-know is recognized in the Act, see section 16, sub-section 5. The "therapeutic exception" does not apply and physicians are not in any case entitled to withhold information about the patient's state of health except in situations where the patient explicitly refer to the right not-to-know..

As part of the right to receive information, patients must be informed about the available options in regards to treatment and care, and is entitled to choose among these options. If the hospital does not offer a specific kind of treatment, the patient must be informed about the possibility to receive treatment at other hospitals. Patients are entitled to seek treatment at any public hospital in Denmark and not only in the county of residence, see section 86 of the Health Act. Furthermore, patients have an extended right to free choice in situations where the regional hospital is not able to provide treatment within 1 month. In this situation the patient is entitled to seek treatment at certain private clinics and hospitals in Denmark or abroad, see section 87. Patients also have the right to freely choose his or her GP.

6.5 Right to give consent

According to section 15 of the Health Act no treatment may be initiated or continued without the patient's informed consent. Derogations only apply in situations where this is established by special laws (compulsory psychiatric care) or follows from section 17-19 of the Health Act, that is in emergency situations or when proxy consent is needed (se further below). Patients may at any time withdraw their consent. The patient's consent must be given voluntarily and for a specific treatment. It is not possible to give an advance directive except in regards to terminal treatment. An oral consent is sufficient in cases of ordinary treatment, whereas written consent is required in special situations such as abortion, organ donation, participation in medical experiments and assisted procreation. Consent must normally be given expressly, but implied consent may be acceptable in regards to certain partial interventions where the patient is adequately informed, and where there is no doubt that the patient accepts the treatment. The patient's consent must be recorded in the medical record.

6.6 Rights related to the patient's medical record

Physicians and certain other health care professionals are obliged to keep medical records about all patients to whom he or she provide healthcare services, see section 21-25 in the Act on Authorization of Health Care Professionals and of Provision of Healthcare. The medical record shall contain information which is necessary in order to provide good and safe care. Detailed rules concerning data which must be recorded, is laid down in an administrative order (Order No. 1373 of 12 December). A medical record can be kept in paper or in

electronic format, see section 23 of the Act. The medical record must be archived at least 10 years after the last recording of information in the record, see section 25 of the Act.
Patients' right to access their own medical records is stipulated in section 37-38 of the Health Act (see above in chapter 5.3). A patient's request to access his medical record shall be assessed as soon as possible. If it is not possible to approve or deny the request within 10 days, the institution or health care professional must inform the patient of this and of the expected time frame for a decision.
Patients always have a right to obtain a copy of their medical records. In regards to hospital records there is normally no charge for the first copy, whereas GP's in certain situations may require the patient to pay for the copies at a price stipulated in an administrative circular.
Normally the patient's relatives do not have right to access information about the patient. However, in regards to relatives to a deceased patient it is stipulated in section 45 of the Health Act that relatives are entitled to be informed about the history of the illness, the cause of death and the way of death provided this is not considered to be against the wishes of the deceased patient.

6.7 Right to protection of privacy and intimacy

Patients' right to protection of privacy and intimacy is described in details in chapter 5.2. The right to privacy is stipulated as a patient's right in section 40 of the Health Act and is also reflected in section 2 of the act according to which the Act in general aims at putting down the requirements in regards to respect for the patient's integrity and autonomy.

6.8 Right to representation in case of incompetence

The Act on Health lay down special rules concerning the protection of patients who are legally or factually incapacitated. According to section 17 of the Act, patients are entitled to give an informed consent when they have reached the age of 15. The patient's parents must normally also be informed until the patient reaches the age of 18, and they should be involved in the decision making. However, it is the minor patient who makes the final decision whether to accept or refuse treatment. In cases of minor patients under the age of 15, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient must be informed and involved in the decision making bearing in mind his or her age and maturity. In regards to adult patients who are permanently incompetent informed consent must be obtained by the closest relative(s) or by a legal guardian. The Act does specify who belongs to the group of closest relatives, but according to the travaux préparatoire it has to be assessed in each individual case. Normally, the patient's spouse or cohabitating partner, the parents or the children will be considered the closest relatives.

7 Identity management in the health sector

Since 1968 all Danish citizens have been provided with a national personal identification number the so-called CPR-number. The number is mandatory and is issued at birth. Persons with a residence permit receive a personal identification number in connection with their permit. The national personal identification number is used as identifier in all parts of the public sector and in the finance sector as well. The information in this chapter is primarily based on the IDABC-report referenced under [RD9].

7.1 Overview

The Danish eIDM system is based on a combination of the central personal identification number and the central National Register (CPR-registeret). The National Register contains comprehensive information about the citizens, including information about name, address, birth registration, citizenship, marital status, kinship and relations to the national church. More detailed information is available through the register's website http://www.cpr.dk/cpr/site.aspx?p=34 .

There is no national identity card in Denmark, but all persons who reside in Denmark are provided with a Health Card which is used in the health care sector in connection with treatment and care. The Health Card replaces the Social Security Card but has the same function.

A digital signature was introduced as part of the Danish eGovernment strategy in 2003. The digital signature is used as identifier in both the public and the private sector. A number of services provided at the national eHealth platform for patients and health care professionals require use of a digital signature.

7.2 The central personal identification number

The central personal identification number was introduced in Denmark in 1968. The number is issued at birth and non-citizens with a residence permit are also provided with a personal identification number. The personal identification number is used as an identifier by all public authorities, in the finance sector and by a number of other actors. Processing of the central personal identification number is regulated in the Act on Processing of Personal Data. According to section 11 of the Act public authorities are allowed to process personal identification numbers with a view to unambiguous identification or as a file number. Private persons or bodies are only entitled to process personal identification numbers if it follows from law or regulation, if the data subject has given his or her consent, if the processing is carried out solely for scientific or statistical purposes or if the processing is a natural element of the ordinary operation of companies, etc. of the type mentioned and the disclosure is of decisive importance for an unambiguous identification of the data subject or the disclosure is demanded by an official authority. The central personal identification number is used as identifier in the entire health care sector – both in the private and in the public part of the

sector. All patient records must include information about the patient's personal identification number, see section 8 in Order No. 1373 of 12 December.

7.3 Health Card

The Health Card was introduced in 2007 as a substitute for the social security card. The card contains information about the patient's personal identification number, name and address, name of doctor, social security category and municipality. The Health Card is widely used in the health care sector as an identifier, and it is also used in other settings as identifier, e.g. at the public libraries. Apart from functioning as a identifier in connection with the provision of treatment and care, the Health Card also gives access to health care free of charge in the health care sector.

7.4 Patient identifier

As noted above, identification of the patient is primarily based on the central personal identification number supplemented with the Health Card. In addition patients can have access to certain special services in the health care sector using a digital signature. The national eHealth platform – sundhed.dk – provides for a number of services to patients with a digital signature. It is possible to get direct access to the patient's Personal Medicine Profile and to have information regarding all contact to the hospital sector. Furthermore, patients can register as organ donors and register a living will using their digital signature. Finally, it is possible to have secure electronic contact with GP's and other health care professionals using the digital signature. More information is provided at the official website of the eHealth platform
http://www.sundhed.dk/wps/portal/_s.155/1921?_ARTIKELGRUPPE_ID_=1023050919180045

7.5 Authentication of healthcare professionals

Authorized health care professionals with a legal diploma are registered in the national register of authorization, which has been set up by National Board of Health. This register contains information about the name, date of birth, occupation, specialization of a health care provider and authorization identification.
http://www.sst.dk/Uddannelse/Autorisationsforhold/Autorisationsregister.aspx?lang=da (only in Danish). The register is available online.
Until 2005 health care professionals' personal identification number was used as an identifier. Since 2005 all authorized health care professionals are provided with a unique identifier called "autorisationsID". The identifier is used in connection with contact to the National Board of Health regarding issues related to the legal diploma, education etc. It is planned that the identifier in the future will be integrated in all situations where unique identification is necessary or relevant. More information is available at this website
http://www.sst.dk/Uddannelse/Autorisationsforhold/AutorisationsID.aspx?lang=da (only in Danish)

Health care professionals are able to access data and services at the national eHealth platform using a special digital signature. The digital signature gives access to information about patients in the Personal Medicine Profile, access to analytic results from laboratories, and access to electronic records from a number of regions. Furthermore it provides for secure electronic communication with the patient.

7.6 Exchange of health-related data

The internet based Danish Health Data Network provides a possibility for extensive communication between health care professionals and health care providers. The Network can be used to e.g. establish web service communication, consult databases and exchange images. The Health Data Network has established connections between existing "secure" data nets in different parts of the health care sector (e.g. regions, Municipality of Copenhagen, Ministry of Health, Sundhed.dk, pharmacies). The Health Data Network consists of a central node which all the traffic passes through between the various agencies. To be connected to the Network user must have an encrypted VPN-connection via the internet or a permanent connection from their own secure network. Further information about the Health Data Network can be found at MedCom's website http://www.medcom.dk/wm109991 .

8 Electronic prescription

Use of prescription is regulated in administrative Order No. 155 of 20 February 2007. According to section 1 of the Order prescription of medicine may take place in the form of a written prescription which can be handed over to the patient or communicated to the pharmacist electronically or by telefax. A prescription may also be communicated by telephone. Section 5 of the Order stipulates that any prescription needs to be signed and dated by the physician or by the dentist. Electronic prescriptions do, however, not need to be signed (see section 20 of the Order). The Order stipulates detailed rules regarding the content of the prescription.

Since February 2007 the Personal Medicine Profile has been supplemented by a Prescription Server. All electronic prescriptions are transferred to the Prescription Server which is connected to the Personal Medicine Profile. The pharmacies have access to the Prescription Server, and can deliver pharmaceuticals to patients on the basis of the prescription. The patient can obtain the medicine at any pharmacy and does not need to decide in advance which pharmacy to use. The prescriptions is stored in the server which means that the patient does not need him or herself to keep the prescription in situations where the prescriptions covers several dispenses of medicine.

There are no special regulations regarding the use of electronic prescriptions. The general rules in the Act on Processing of Personal Data together with the Health Act apply regarding processing of health information and use of prescription apply.

9 General assessment[1]

Denmark has been characterized as one of the forerunners in the field of eHealth, and in many areas the use of eHealth is certainly very advanced, although there is still room for improvement. Seen in this perspective it is somehow surprising that neither the national health authorities nor the Parliament has shown interest in developing a comprehensive regulatory framework for the use of eHealth services. It could be argued that the existing legal instruments are able to deal with issues raised by use of eHealth and that the regulatory framework is – and should be - "technology neutral". However, there may be good reasons to reflect on, whether this approach is well considered. First of all it is uncertain to which extent existing legal requirements, e.g. regarding patients consent, are complied with in connection with the use of eHealth services. In general, Danish physicians are not well informed about patients' rights, and when technological tools provide for easy communication, there is a risk that legal rules are set aside. Secondly, some regulatory adjustments have already proved to be necessary when existing rules was considered to be an impediment for use of eHealth technologies. These adjustment has been introduced step by step, which means that they are not based on a comprehensive analyses where the rights of patient's and privacy issues has been balanced against the interest in efficiency and quality improvement. Thus, there seem to be good reasons for reflecting on the regulatory framework. In this regard it is positive that the latest National eHealth Strategy focuses on the relation between the technological development and the patient's right to privacy and safety and on how technological solutions may be used to ensure compliance with the legislation.

For the development of cross-border eHealth services, the Danish legal landscape contains only few specific peculiarities. The transposition of the European data protection directive into Danish law follows quite closely the terminology of the Directive and only few additional requirements, compared to the EU Directive, have been added for the processing of personal data concerning health.

Mette Hartlev
27 June 2008

[1] Note of the editor: The Danish Ministry of Health and Prevention has communicated that it does not share professor Mette Hartlevs points of view in the following paragraph. The Ministry of Health and Prevention finds the ambition to develop a legal framework that to take all - also the upcoming - eHealth services into consideration somewhat idealistic but hardly realistic. And on the contrary the Ministry of Health and Prevention finds it to be most according to the patients' rights to privacy and safety that upcoming eHealth services is constantly considered in the context of the existing legal framework so that any changes in the legal framework is thoroughly considered.

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