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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE SWEDEN

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European Commission
Directorate General Information Society

Brussels

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1.1 Applicable Documents

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

1.2 Reference Documents

[RD1]	Communication from the Commission, e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area, 2004 http://ec.europa.eu/information_society/doc/qualif/health/COM_2004_0356_F_EN_ACTE.pdf
[RD2]	eHealth Action Plan, Progress Report http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-ap-prog-report2005.pdf
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[RD7]	Report on Priority Topic Cluster One and Recommendations: Patient Summaries, http://www.ehealth-era.org/documents/eH-ERA_D2.3_Patient_Summaries_final_15-02-2007_revised.pdf
[RD8]	Pilot on eHealth indicators: 'Benchmarking ICT use among General Practitioners in Europe (Empirica), final report: http://ec.europa.eu/information_society/eeurope/i2010/docs/benchmarking/

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

2 Glossary

2.1 Definitions

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

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

OCSP	Online Certificate Status Protocol
PKI	Public Key Infrastructure
NRN	National Register Number
SIS	Social (security) Information System
SSCD	Secure Signature Creation Device
SSIN	Social Security Identification Number
TTP	Trusted Third Party

3 Introduction

3.1 General overview of the Swedish healthcare system

A comprehensive and rather recent (2005) overview of the Swedish healthcare system can be found in the Swedish HiT country report published by the European Observatory on Health Systems and Policies (written by Glenngård AH, Hjalte F, Svensson M, Anell A, Bankauskaite V.)
http://www.euro.who.int/Document/E88669.pdf (145 p.)

From the executive summary and the introduction of this report, we reproduce the following important observations:
"The Swedish health care system is organized on three levels: national, regional and local. The regional level, through the county councils, together with central government, forms the basis of the health care system. The county councils plan the development and organization of health care according to the needs of their residents. Their planning responsibility also includes health services supplied by other providers, such as private practitioners and physicians in occupational medicine."
"The Swedish health care system is primarily funded through taxation. Both county councils and municipalities have the right to levy proportional income taxes on their respective populations. In addition to taxation revenue, financing of health care services is supplemented by state grants and user charges. The social insurance system, managed by the Swedish Social Insurance Agency, provides financial security in case of sickness and disability. No basic or essential health care or drug package is defined within Swedish health care."
"The aim of primary care is to improve the general health of the population and to treat diseases and health problems that do not require hospitalization. General practitioners provide treatment, advice and prevention. It is up to each county council to decide how to serve its population with primary care. Primary care is mainly publicly provided. The National Institute of Public Health is responsible for running health promotion and disease prevention programmes at the national level. Preventive and population-oriented health care has been integrated into primary health care."
"In Sweden a relatively large proportion of the resources available for medical services have been allocated to the provision of care and treatment at the hospital level. For highly specialized care, Sweden is divided into six large medical care regions, within which the county councils cooperate to provide the population with highly specialized care."
"Resource allocation principles vary among the county councils. Most county councils have decentralized a great deal of the financial responsibility to health care districts through global budgets. [..] The majority of health care providers are publicly owned, and therefore physicians, dentists, pharmacists and other professional groups are mainly salaried employees."
"The health system is primarily funded through taxation. Both the county councils and the municipalities levy proportional income taxes on the population to cover for the services that

they provide. The county councils and the municipalities also generate income through state grants and user charges. The mechanisms for paying providers vary among the county councils, but payments based on global budgets or a mix of global budgets and per-capita payments are the most commonly used systems."

3.2 Use of ICT in the Swedish healthcare sector

A recent (2007) status of the use of ICT by *general practitioners* in Sweden 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 Swedish country brief, we take over the following key findings:
"In terms of infrastructure, virtually all Swedish GP practices use a computer. Almost the same share, that is 99% of practices, disposes of an Internet connection. In Sweden, broadband represents the most common form of access to the Internet with 88% of GP practices resorting to broadband connections."
"In contrast to most other European countries, Sweden scores well above average with regard to nearly all aspects of eHealth use covered by the survey. The only exception is the use of a computer for consultation. In this exceptional case, Sweden displays substandard results. While in 62% of the GP practices a computer is available in the consultation room, it is actually used for consultation purposes with the patients in only 47% of the practices."
"Decision Support Systems are extensively used in Sweden: more than 85% of Swedish GP practices use them either for prescription or diagonis reasons."
"The storage of electronic patient data is common practice in Sweden. Virtually all GP practices store at least one type of of medical patient data in digital form. With regard to the storage of the different types of medical patient data Sweden also shows results that are above the EU27 averages. Administrative patient data is registred in 96% of the practices."
"The use of networks for the transmission of electronic administrative and medical patient data is less well established. 13% of Swedish GP practices transfer medical data to other care professionals and 16% exchange administrative data with other carers. These results are only slightly above average. With regard to the exchange of administrative data with reimbursers, Sweden does not exceed the EU27 average of 10%. An exception in the field of electronic data transfer is the reception of analytic results from laboratories. 82% of Swedish GP practices receive laboratory results electronically; a share which amounts to two times the Euoropean average."
"Especially remarkable in Sweden is the high prevalence of ePrescribing, which is used in 81% of the GP practices. Only Denmark achieves even higher usage rates. Sweden is also the country with the highest occurrence of telemonitoring in Europe, even if this concerns only 9% of the GP practices."

3.3 National eHealth strategy

An overview of the Swedish eHealth policy can be found in the September 2007 ERA Report "eHealth strategy and RTD progress in Sweden" (Author(s): Hannele Hyppönen, Persephone Doupi, Emmi Tenhunen, National Research and development Centre for Welfare and Health (STAKES), Helsinki Finland): http://www.ehealth-era.org/database/database.html#sweden

For our Study, the following observations, adapted from this report, are important:

Traditionally, eHealth solutions in Sweden have been developed in co-operation of national and regional authorities (counties) on a voluntary basis, without a common national eHealth Strategy. The organisation "Carelink" (established in 2000) was assigned to operate as a link between regional initiatives, advancing the use of IT in healthcare. Its board of directors consists of representatives from municipalities, counties, the National Board of Health and Apoteket AB (Swedish Pharmacy Chain).[1]

In 2005 the Ministry of Health and Social Affairs, the Swedish Association of Local Authorities and Regions, the National Board of Health and Welfare, the Medical Products Agency, the National Corporation of Swedish Pharmacies and Carelink established a national High Level Group for eHealth to develop a national eHealth strategy. The strategy was published in March 2006 and is available (in English) at http://www.sweden.gov.se/content/1/c6/06/43/24/f6405a1c.pdf.

The strategy outlines six action areas that group the necessary improvements that must be achieved in order to realise the strategy's aims. These action areas are

1. Bringing laws and regulations into line with extended ICT use
2. Creating a common information structure
3. Creating a common technical infrastructure
4. Facilitating interoperable, supportive ICT systems
5. Facilitating access to information across organisational boundaries
6. Making information and services easily accessible to citizens

According to the eHealth strategy "increased ICT use cannot be achieved without basic improvements, including a uniform information structure, extended technical infrastructure and legislative change. Action in these areas will yield substantial benefits for e-Health solutions of all types. ICT-based tools used in health care work and for communication between patients and care services also need improving."

When it comes to bringing laws and regulations into line with extended ICT use (Action area 1) the strategy mainly outlines amendments necessary to minimise the risk of unwarranted intrusion into patient's personal privacy. Recent changes in legislation have primarily focused on the use of personal data within the health sector and the protection of patient confidentiality and privacy.

[1] Carelink is a voluntary association – Carelink Association – where the county councils, regions, local authorities and private providers of care are invited to become members. In the summer of 2007, Carelink had seventy members; including all twenty-one county councils, forty-two local authorities and seven private healthcare corporations. Carelink's members contribute towards improving health care and nursing services, supported by an effective use of IT. See more at http://www.carelink.se/en/.

Regarding action area 2 and 3 some of the improvements already achieved include the creation of a joint telecommunication network within health care, called Sjunet, as well as an ePrescription system and telemedicine applications.
Since 2002 all Swedish hospitals and primary care centres have been connected with Sjunet. The network links together county councils and regions, pharmacies as well as several other health care enterprises. In other words it connects all the 80 public hospitals, 800 primary care centres, 950 pharmacies and a number of private health care institutions.
Sjunet is a fibre-optical network separate from the Internet, which allows for the secure and reliable exchange of confidential data, including images. It also incorporates the possibility for video conferencing. Other features include order entry, a national phone directory, a knowledge database, clinical care planning and remote diagnostic services. Sjunet won the eEurope award for eHealth in 2003.
Another eService supported by Sjunet is the ePrescription system. In April 2006 the amount of ePrescriptions reached 55%. Also telemedicine has been tested and/or used in over 100 applications and more than 75% of hospitals have tested or are already using telemedicine applications.
On the regional level electronic catalogues of and about service providers are being developed and linked nationally through services address register (HSA catalogue). A secure email system is in use in many counties.
The SITHS-project has developed secure IT authentication solutions for health care professionals. The National Patient Advice project has developed a Health Portal for citizens. ELak, a network led by Carelink supports further development of electronic communication between the health service, care and pharmacies.
A follow-up report on the national eHealth strategy by the Swedish government outlined some achievements and some improvements that are still ahead:[2]
All county councils have adopted the national eHealth strategy. When it comes to municipalities, less than half have adopted the national plan, therefore an increased co-operation is suggested.
The recently enacted Patient Data Act creates better legal conditions for the exchange of information between health care providers while at the same time ensuring the patients's personal integrity (more in detail below).
Regarding the creation of a common infrastructure (action area 2) several projects have been initiated or already fully implemented. For example the co-operation between health care and the national population register (administered by the Swedish National Tax Board) (VIF) is ongoing, a national format for ePrescriptions (NEF) is being implemented at the moment and a national common terminology for health care (Snomed CT) is expected to be realised in 2011.
Within action area 3 Sjunet is already implemented and being expanded to more health care providers. The health care professional database (Hälso- och Sjukvårdens Adressregister (HSA) provides the necessary information on the personell's work tasks and authority and is

[2] The report can be downloaded (in Swedish) at http://www.regeringen.se/sb/d/10671.

being implemented in several county councils as well as municipalities. The same can be said about SITHS, the secure eHealth project of Carelink, aiming at providing health care professionals with digital certificates linked to their authority within the organisation. Another application being procured is a videoconferencing system, which allows up to 12 persons to interact on a distance.
Within action areas 4 and 5 the National Patient Overview can be mentioned. In spring 2008 the Swedish Healthcare Advisory Organization (*Sjukvårdrådgivningen*) procured TietoEnator to develop and implement a national electronic health record system, known as National Patient Overview (NPO). The system will, at a later stage, allow Swedish residents to access their own medical records through the Internet. The NPO will take advantage of the InterSystems HealthShare software, a health information network platform.
Action area 6 (Making information and services easily accessible to citizens) includes the already existing Swedish Healthcare Advisory platform that helps patient with information on health care and tries to improve the patient's participation in the treatment.[3] Another initiative is a handbook for nurses that should help hospital personal in their daily work.

3.4 Regulatory framework for patients' summaries

There is no specific legislation in Sweden dealing with electronic patients's summaries. The, above-mentioned, project National Patient Overview (NPO) is, however, aiming at a national patient summaries database.[4] Until recently, the legal obstacles concerning electronic patient summaries and exchange of data between different care providers were unclear. The new Patient Data Act (*patientdatalag*), in force since 1 July 2008, aims at removing these obstacles.

There are also several specific acts dealing with different databases containing health data held by public authorities, e.g. the (until recently in force) Care Registers Act (*lag (1998:544) om vårdregister*), and the Act on Databases held by the Social Services.

3.5 Regulatory framework for telemedicine

There is no general legal framework dealing with telemedicine. The general rules on health care apply both to traditional health care as well as to care utilising IT applications. Certain regulations may also include specific rules on telemedicine, see below e.g. the Regulation on prescription and delivery of medicine stipulating rules on prescriptions via the telephone.

3.6 Regulatory framework for electronic prescriptions

In Sweden the Medicinal Products Act (SFS 1992:859) and the Medicinal Products Ordinance (SFS 1992:1752) regulate the prescription of medicine in general. The Medical Products

[3] The website is available at http://www.sjukvardsradgivningen.se/

[4] More information at http://www.npö.nu/

Agency (*Läkemedelsverket*)[5], which is the national authority responsible for the control and supervision regarding medicinal products, cosmetic and hygiene products and medical technical products, issues furthermore specific regulations when it comes to medicine.
The Regulation on prescription and delivery of medicine (*Läkemedelsverkets föreskrifter om förordnande och utlämnande av läkemedel m.m. (receptföreskrifter); 1997:10*)[6] stipulates the requirements for prescriptions, both paper-based as well as electronic prescriptions.
A system for electronic prescriptions has been in use though for quite some time. For a summary see eHealth IMPACT - Descriptive report on site study results: Apoteket and Stockholm County Council, Sweden – eRecept, an ePrescribing application, February 2006.[7]

3.7 Overview of relevant legislation

Until recently the legislative framework governing electronical medical records comprised the Patient Records Act (1985:562, *patientjournallagen*) and the Health Care Register Act (1998:544, *lagen om vårdregister*). Since 1 July 2008, however, the newly enacted Swedish Patient Data Act (SFS 2008:355, *Patientdatalagen*) replaced these two statues.
The Patient Data Act both regulates the legal obligation to file medical records for each patient as well as the legal requirements for processing of personal data within the health sector. The first part of the statute concerning the filing of medical records is applicable for both paper and electronic records, whereas the parts on processing of personal data focus on processing by automated means.
Both the Patient Data Act as well as the Swedish Personal Data Act (SFS 1998:204, *personuppgiftslag*) stipulate detailed rules on processing of personal data, secrecy of personal data and the requirements for the processing. In addition several other statutes and ordinances regulate certain databases containing personal medical data, such as e.g. biobanks (Biobanks in Medical Care Act, SFS 2002:297).
Legislation regulating health care in general, such as the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*) and the Health and Medical Services Act (SFS 1982:763, *hälso- och sjukvårdslagen*) is dealing with the legal requirements to practice medicine in Sweden as well as the various obligations of care providers and health care professionals. In addition, the Secrecy Act (1980:100, *sekretesslagen*) stipulates the principle of confidentiality for public health care providers.

[5] http://www.lakemedelsverket.se/Tpl/StartPage____395.aspx

[6] Available in Swedish at http://www.lakemedelsverket.se/upload/lvfs/konsoliderade/LVFS1997_10%20omtryck.pdf

[7] http://www.ehealth-impact.org/case_tool/data/binary/d9448cc8ce8d4b44ab01f211908dd02f.pdf

4 Regulatory framework for the healthcare profession

The rights and duties of healthcare providers and patients are regulated in the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*). The Act deals with the obligations of healthcare employees, the requirements for the practice of medicine in Sweden, professional liability, the supervision by the National Board of Health and Welfare (*Socialstyrelsen*) as well as by the Medical Responsibility Board (*Hälso- och sjukvårdens ansvarsnämnd*).

4.1 Legal conditions for the practice of healthcare

The practice of medicine and the necessary legal requirements for doctors are regulated in the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*).

In order to be able to practice medicine in Sweden, one has to have the appropriate university degree, sucessfully participated in the necessary traineeship and be approved by the National Board of Health and Welfare (*Socialstyrelsen*). Only doctors who have been approved and received their license are allowed to practice medicine.

In Sweden medical education and training are organised in three phases: undergraduate education, pre-registration training and specialist training. After graduation of the basic medial education follows a compulsory training programme (internship) of at least 18 months. After successful completion of this programme the doctor obtains his licence to practise (full registration), which is granted by the National Board of Health and Welfare.

Once the doctor has got a licence to practise, the doctor is entitled to apply for a post to start his/her specialist training. The specialist training lasts a minimum of five years and is carried out in a salaried position with medical responsibility.

In order to be registered and receive a full license, one has to apply to the National Board of Health and Welfare (*Socialstyrelsen*)[8] and provide the following documents:

- evidence of qualification as listed in the Service Directive presented in copies verified by an authority in Sweden or in the Member State of origin
- certificate of good standing with the competent authority in the Member State of origin or last residence. This certificate must not be older than three months and be presented in original. This requirement is not applicable to migrating doctors from a Nordic State since other routines are applied.

When the National Board of Health and Welfare (*Socialstyrelsen*) has made the formal assessment, the applicant will become fully registered and the licence to practise medicine will be issued.

Only the following professionals are allowed to practice within their profession (this sole right also includes the protection of the professional title): doctor (physician), dentist, midwife, pharmacist and dispenser.

[8] http://www.socialstyrelsen.se/en/

4.2 Control over the practice of medicine

In Sweden the National Board of Health and Welfare (*Socialstyrelsen*) (http://www.socialstyrelsen.se/en/) is the national supervisory authority for social services, public health, the prevention of infectious diseases, and health and medical care.

4.3 Professional liability

A doctor who is practising medicine in Sweden is obligated to exercise his profession in accordance with the scientific development and reliable experience (Chapter 2 Section 1 of the Professional Activities in the Health and Medical Care Field Act). As there is no legal definition of this concept an explanation of "scientific development and reliable experience" has to be derived from administrative provisions governing the professional duties as well as individual decisions of the Medical Responsibility Board (*Hälso- och sjukvårdens ansvarsnämnd*)[9].

If the doctor fails in his professional duty, intentionally or negligently, and the fault is more than trivial, the Medical Responsibility Board may impose disciplinary sanctions (a reminder or a warning) after notification from the National Board of Health and Welfare or the patient concerned. In serious cases the licence to practise may be revoked and the doctor removed from the medical register.

The Swedish Medical Association (*Sveriges Läkarförbund*)[10] also adopted a code of methical ethics.

All patients, in public as well as in private care, are covered by an insurance ("Patient Insurance") paid by the county councils and other care providers. The insurance gives the patient economic compensation for injuries that occur in connection with medical examination, treatment and care. It operates on a no-fault principle, i.e. the patient does not have to prove that the injury is due to negligence on the part of the physician or other personnel.

4.4 Professional secrecy

Secrecy about information on the patient is one of the most important obligations for physicians. In Sweden this principle is regulated in two statutes as well as several special laws. Both the Secrecy Act (SFS 1980:100, *sekretesslagen*) as well as the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*) contains rules about the secrecy of patient information.

As many health care providers are public authorities the Secrecy Act applies, stipulating exceptions to the general principle of openness. In case of a private healthcare provider the Professional Activities in the Health and Medical Care Field Act applies. The rules are, however, similar and basically prescribe that secrecy applies to all information about a

[9] http://www.hsan.se/

[10] http://www.slf.se/

patient. One of the few exceptions includes transfer of health data between public care providers if the conditions of the Patient Data Act are met.
All personell working at the care provider, including the administrative and technical staff, is obliged to follow the rules of the Secrecy Act or the Professional Activities in the Health and Medical Care Field Act respectively.
Also the Swedish Patient Data Act contains rules concerning the secrecy of patient information. For example only personell involved in the treatment of a patient may access the his health data.

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

The first legislation regulating the processing of personal data, mainly within the public sector, was the Swedish Data Act (SFS 1973:289, *datalag*). When transposing the European Directive 95/46/EC into Swedish law the Swedish Data Act was replaced and the new Personal Data Act was enacted.[11]

The Swedish Personal Data Act (SFS 1998:204, *personuppgiftslag*) corresponds to the Directive rather closely, both in its structure as well as in its wording. Some peculiarities are for example the exemption with regards to the freedom of the press as well as the Swedish principle of openness:

> Section 7
> The provisions of this Act are not applied to the extent that they would contravene the provisions concerning the freedom of the press and freedom of expression contained in the Freedom of the Press Act or the Fundamental Law on Freedom of Expression.
> The provisions of Sections 9–29 and 33–44 and also Section 45, first paragraph, and Sections 47–49 shall not be applied to such processing of personal data as occurs exclusively for journalistic purposes or artistic or literary expression.
>
> *Relationship to the principle of public access to official documents*
> Section 8
> The provisions of this Act are not applied to the extent that they would limit an authority's obligation under Chapter 2 of the Freedom of the Press Act to provide personal data.
> Nor do the provisions prevent an authority from archiving or saving official documents or that archive material is taken care of by an archive authority. The provisions of Section 9, fourth paragraph, do not apply to the use by an authority of personal data in official documents.

In 2006, some amendments were introduced, excempting certain processing of personal data from the strict rules of the Personal Data Act and placing it under the principle of misuse.[12] The new regulation allows processing of personal data that does not form part of and is not intended to form part of a set of personal data that has been structured in order to significantly facilitate searches for or compilations of personal data (the new Section 5a of the Personal Data Act), i.e. in practice personal data registers and personal data-related databases.

In other words, the handling regulations of the Personal Data Act would not be applicable, inter alia, to everyday processing like the production of linear text in word processing software, the publication of linear text on the Internet, the use of sound and image recordings and email correspondence provided that the material is not intended for inclusion in a database with a personal data-related structure such as an electronic system for the management of a business. The amendment was deemed to be within the framework of the Directive.

In contrast to the general rules of the Personal Data Act, the new regulation penalises the misuse of personal data, i.e. the processing is allowed unless it involves an improper intrusion

[11] A full version of the Swedish Personal Data Act, however not updated with the last amendment in 2007, is available in English at http://www.sweden.gov.se/content/1/c6/01/55/42/b451922d.pdf

[12] A short summary of the governmental proposal is available in English at http://www.sweden.gov.se/content/1/c6/01/55/42/24980a18.pdf

on somebody's personal integrity. An intrusion might exist if the data was processed for improper purposes, such as persecuting or disgracing an individual; if a large amount of information about one individual was collected without acceptable reasons; in case of slander or a violation of secrecy. In case of misuse, the registered person has the right to receive compensation for damages.
In addition, as has been the case, a registered person still has the right to subject access, i.e. to obtain on request a "data extract" including the personal data processed. The general exception being that it proves impossible to provide a data extract or it would require disproportionate effort to do so because, it is, for instance, difficult to find information about a particular person in text and in sound and image recordings.
The responsible supervisory authority according to the Directive is the Swedish Data Inspection Board (*Datainspektionen*, http://www.datainspektionen.se/in-english/).

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

The definition of sensitive data according to Article 8 of the Directive corresponds to the types of information mentioned in Section 13 of the Swedish Personal Data Act:

> *Section 13*
>
> It is prohibited to process personal data that reveals
>
> a) race or ethnic origin,
> b) political opinions,
> c) religious or philosophical beliefs, or
> d) membership of a trade union.
>
> It is also prohibited to process such personal data as concerns health or sex life.
>
> Information of the kind referred to in the first and second paragraphs is designated as sensitive personal data in this Act.
>
> *Exemptions from the prohibition of processing sensitive personal data*
>
> *Section 14*
>
> Despite the prohibition of Section 13 it is permitted to process sensitive personal data in those cases stated in Sections 15–19.
>
> In Section 10 there are provisions concerning the cases in which processing of personal data is not permitted in any case whatsoever.
>
> *Consent of publicizing*
>
> *Section 15*
>
> Sensitive personal data may be processed if the registered person has given his/her explicit consent to processing or in a clear manner publicised the information.
>
> *Necessary procession*

Section 16

Sensitive personal data may be processed if the processing is necessary in order that

a) the controller of personal data should be able to comply with his/her duties or exercise his/her rights within employment law,

b) the vital interests of the registered person or some other person should be able to be protected and the registered person cannot provide his/her consent, or

c) legal claims should be able to be established, exercised or defended.

Information that is processed on the basis of the first paragraph a) may be disclosed to a third party only if there is within employment law an obligation for the controller of personal data to do so or the registered person has explicitly consented to the provision.

Health and hospital care

Section 18

Sensitive personal data may be processed for health and hospital care purposes, provided the processing is necessary for

a) preventive medicine and health care,
b) medical diagnosis,
c) health care or treatment, or
d) management of health and hospital care services.

A person who is professionally operational within the health care sector and is subject to a duty of confidentiality may also process sensitive personal data that is subject to the duty of confidentiality. This also applies to the person who is subject to a similar duty of confidentiality and who has received sensitive personal data from the operation within the health care sector.

Section 18 is supposed to correspond to Article 8.3 of the EC Directive. Both contain the same types of accepted purposes, Article 8.3 does, however, in contrast to Section 18, not mention that the processing should take place for health and hospital care purposes.

In addition, the recently introduced Swedish Patient Data Act (SFS 2008:355, *patientdatalagen*) contains detailed rules on the processing of personal data within the health sector (see more below).

As earlier mentioned the Health Care Register Act (SFS 1998:544, *lagen om vårdregister*) as well as the Health Records Act (SFS 1985:562, *patientjournallagen*) were recently replaced by the Swedish Patient Data Act (SFS 2008:355, *patientdatalagen*). Previously the Health Care Register Act regulated the processing of personal data within health care whereas the Health Records Act contained rules with regards to patient journals.

The new Patient Data Act tries to combine both laws and stipulates on one hand the rules for the legitimate processing of personal health data and on the other hand the legal requirements concerning patients' journals.

In specific, the Patient Data Act introduced a coherent patient journal. This means, inter alia, that care providers can access eath other's information if they fulfill the requirements of the Act. One of the requirements is that only those who need the information in their health care are allowed to access the patient's data (internal secrecy). The Act also sets up rules for different levels of access rights as well as controll of access. The patient has the right to lock his data both within a certain database as well as towards other care providers. Finally, the Act also allows patients to access their own health data via the Internet.

The Act is complemented with the Patient Data Ordinance (SFS 2008:360, *patientdataförordningen*), as well as with more specific rules from the National Board of Health and Welfare (*Socialstyrelsen*).

5.3 Information and access rights of data subjects

Despite the general access rights of the Swedish Personal Data Act (Section 23-27), the Swedish Patient Data Act (SFS 2008:355, *patientdatalagen*) regulates access rights specifically with regards to health data.

Chapter 8 of the Patient Data Act deals specifically with the rights of the individual. According to Section 2 the patient's journal shall as soon as possible be released to the patient or a near related person unless otherwise stipulated in Chapter 2 Section 8 or Section 9 of the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*).

Chapter 8 Section 5 of the Patient Data Act stipulates that the care provider shall inform the patient about all access to the patient's data. Section 6 regulates in specific which information shall be given to the individual, e.g. purpose with processing, which categories of data are processed, possible secrecy, and also refers to Sections 26 and 29 of the Personal Data Act.

5.4 Other relevant rules regarding personal data protection

Despite the Personal Data Act, there are, as mentioned earlier, several acts and ordinances containing tailor-made data protection provisions for specific sectors of the public administration or a particular personal data file held by an authority, especially within the health and social service sector, but also for databases held by the police, military services, customs authorities, prison administrations, courts and the labour market authorities. Another example for a specific statute is the Act on the register of vehicles.
More examples within the health sector include the Act on Health Data Registers (SFS 1998:543, *lagen om hälsodataregister*) that regulates the use of personal health data in different databases held by public authorities. The aim of these databases is not the health care of individuals but rather research and epidemiological surveys.
The Act on prescription registers (SFS 1996:1156, *lagen om receptregister*) deals with the administration of prescriptions and the amounts that patients have to pay themselves as well as if a patient reaches the maximum limit for medicine costs.

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the Professional Activities in the Health and Medical Care Field Act (SFS 1998:531, *lagen om yrkesverksamhet på hälso- och sjukvårdens område*) as well as in the Health and Medical Services Act (SFS 1982:763, *hälso- och sjukvårdslagen*).

6.1 Scope of the law

The Professional Activities in Health and Medical Care Field Act deals with the obligations of healthcare employees (Chapter 2), the requirements for the practice of medicine in Sweden (Chapter 3), professional liability (Chapter 4 and 5), and supervision by the National Board of Health and Welfare (*Socialstyrelsen*) as well as by the Medical Responsibility Board (*Hälso- och sjukvårdens ansvarsnämnd*) (Chapter 6 and 7).
The Health and Medical Services Act regulates the general conditions for health care and the competences of both county councils and municipalities.
The Act defines health and medical services as medical measures to prevent, investigate and treat diseases and injuries. This also includes medical transport as well as taking care of diseased. Dental care is regulated in another law. Abortion, inseminations, transplantations and autopsies are also considered health and medical services, but are regulated in specific laws.
The goal for healthcare is according to the Health and Medical Care Field Act good health and equal conditions for everybody (Section 2).
The term “patient” is not defined in either of the Acts.

6.2 Duty of the patient to co-operate

The Health and Medical Services Act does not mention a duty for the patient but rather an obligation for the health professional to perform the treatment and care in cooperation with the patient as far as possible (Section 2 a, see also below).

6.3 Right to quality care

According to Section 2 a of the Health and Medical Services Act healthcare should fulfill the requirements of good care, which, inter alia, entails

- good quality with a good hygienic standard as well as meeting the patient’s need for safety in care and treatment
- easy accessibility
- respect for the patient’s self-determination and integrity
- close contacts between the patient and the healthcare professionals
- meeting the patient’s need for continuity and safety in care.

High quality care entails care in accordance with the prevailing standards as determined by the current state of science.

6.4 Right to free choice

The obligation to provide care does not mean that the patient can decide in which form care should be given, rather this is decided by the health care provider with regards to the need for care of the patient and other fact such as access to available places and priorities with regards to the need of other patients.
According to the Health and Medical Services Act a patient does not have to right to treatment outside the county (Section 3 a) or municipality (Section 18 a) he is living in if the county/municipality can offer the treatment he requires.

6.5 Rights related to information about the state of health

Section 2 b Health and Medical Services Act as well as Chapter 2 Section 2 Professional Activities in the Health and Medical Care Field Act state that the patient should receive individually adjusted information concerning his health status and the methods for examination, care and treatment that exist.
If the information cannot be communicated to the patient, it shall be given to a closely related person of the patient. Exceptions apply, inter alia, with regards to Chapter 7 Section 3 or 6 Secrecy Act (SFS 1980:100, *sekretesslagen*).

6.6 Right to give consent

The word "consent" is not mentioned in the Health and Medical Services Act. Section 2 a of the Act and the obligation for the health care provider to co-operate with the patient and respect the patients self-determination has, however, been interpreted to include a requirement for consent. In other words, nobody can be forced to receive treatment. An exception may be possible if stipulated in legislation. This right also corresponds with Chapter 2 Article 6 The Instrument of Government (SFS 1974:152, *regeringsformen*).

> Art. 6. Every citizen shall be protected in his relations with the public institutions against any physical violation also in cases other than cases under Articles 4 and 5. […]

6.7 Rights related to the patient's medical record

As the Patient Data Act replaced two earlier statutes, some if it's parts apply to both paper-based medical records as well as electronic records. For example, the duty to keep records is mentioned in Chapter 3 of the Patient Data Act. These rules apply despite the fact if the medical record is kept in paperform or in an electronic database. Other regulations of the Act only apply on automated processing of data.

Chapter 8 of the Swedish Patient Data Act contains rules on the rights of the individual. According to Section 2 the patient's journal shall as soon as possible be released to the patient

or a near related person unless otherwise stipulated in Chapter 2 Section 8 or Section 9 of the Professional Activities in the Health and Medical Care Field Act.

Chapter 8 Section 5 of the Patient Data Act stipulates that the care provider shall inform the patient about all access to the patient's data. Section 6 regulates in specific which information shall be given to the individual, e.g. purpose with processing, which categories of data are processed, possible secrecy, and also refers to Sections 26 and 29 of the Personal Data Act.

Chapter 2 Sections 2 and 3 stipulate that the processing of personal data that is allowed according to this Act also is legitimate if the patient does not agree (with a few exceptions). In case the processing is not allowed according to this Act, the patient can expressly agree to the processing.

6.8 Right to protection of privacy and intimacy

One main principle of health care in Sweden is the respect for the individual's self-determination and his privacy (Section 2 Health and Medical Services Act and Chapter 2 Section 1 Professional Activities in the Health and Medical Care Field Act). The health care sector has more limited possibilities than other authorities to release data to other authorities, an example for this beeing Chapter 12 Section 3 Secrecy Act saying that it is not possible to use a balance of interest argument when it comes to health care information. This leads to the fact that quite often a transfer of patient's data only is possible if the patient agrees.

6.9 Right to representation in case of incompetence

Neither the Professional Activities in the Health and Medical Care Field Act nor the Health and Medical Services Act specify rules on representation. Applying general rules, however, one can establish that in the case of minor patients, the patient rights are exercised by the parents or by the patient's guardians while taking into consideration the minor patient's opinion.

7 Identity management in the health sector

At the moment there is no co-ordinated identity management system available for the Swedish healthcare sector. There are several ongoing projects and since 1998 Carelink has worked with PKI solutions within the SITHS-project (Safe IT within the healthcare sector). The project focused on personal eIDs for employees linked to their employment status.
Sweden does not have a national eIDM system administered by public administration. Rather the issuing of eIDs is done by private organisations, mainly banks. The use of eIDs in the health care sector is not yet very common with a few exceptions.

7.1 Overview

As mentioned above, there is no national eIDM system in Sweden. The issuing of eIDs is done by private entities, mainly banks. The last procurement of electronic ID-cards took place in 2008 leading to framework agreements with the following providers for eIDs in Sweden:

- BankID (9 different banks)
- Nordea Bank AB
- TeliaSonera Sverige AB

These eIDM systems are indirectly linked to the population register (*Folkbokföringssystemet*)[13], as one requires a personal identification number in order to obtain an eID. This allows a unique identification of the individual eID holder. Also non-Swedish citizens can acquire a personal identification number if they are registered in Sweden.
VERVA (Swedish Administrative Development Agency) has recently published a report on the future of eIDs in Sweden and suggests a more co-ordinated system in Sweden.[14]

7.2 Swedish eIDM systems

Sweden has had a tradition regarding ID-cards being distributed by private entities. For a long time the Post Office and several banks have issued personal identification cards. Some of the ID-cards issued by banks can be used as carriers for an eID. The eID can, however, also be stored on another smart card or as software on a computer. The ID-card issued by the police follows the standards by ICAO (International Civil Aviation Organization) and contains a chip that can be used in the future to store electronic information, i.e. e-services, as for example the eID. This is, however, left up to the providers within the framework agreement for Swedish eID services.
Depending on the city council or municipality, the eIDs can be used for different public e-services. An example for this is the Healthcare Guide (*Vårdguiden*) offered by the Stockholm County Council. Patients can, via the Internet information portal http://www.vardguiden.se,

[13] The population register is administered by the Swedish National Tax Board (*Skatteverket*).

[14] A summary of the report in English is available at http://www.verva.se/upload/publikationer/2008/Electronic-identification-and-signature-in-Sweden.pdf

renew prescriptions or certificates of illness; make a doctor's appointment; obtain an extract from a patient record; or obtain medical advice from nurses and psychologists/psychiatrists. In order to use the system patients need an eID or obtain a security code. At the moment, the service utilizes eIDs only for authentication and not for signing purposes.

7.3 Patient identifier

As mentioned earlier, identification of Swedish citizens is mainly based on the personal identity number. This will probably be the case when personal health data will be exchanged between care providers.

7.4 Authentication of healthcare professionals

One of the several projects initiated by Carelink has been SITHS, which stands for secure e-Health in Swedish (Säker IT I Hälso- och Sjukvården). SITHS is intended to become the national security solution involving the use of electronic ID cards. AT the moment, a few county councils have introduced SITHS and are testing the applications.
A number of county councils have set up electronic directories for health care professionals. These are used internally by county councils to search for and find contact information on individuals and organisations. Approximately ten catalogues are also linked up nationally through the health and medical care services' address register (the HSA directory), in which affiliated organisations can display some of the contents to other care providers.

7.5 Exchange of health-related data

Sjunet, the Swedish health and medical care services communications network, encompasses the health and medical care principals' network. Today, all county councils, some 40 municipalities and a number of private care providers are members of Sjunet. The network builds the basis for other applications.
Possible legal obstacles have had mainly to do with patient's privacy and integrity but did not hinder any expansion of Sjunet to this point.

8 Electronic prescription

E-prescriptions (electronically transmitted prescriptions) have been increasingly used in Sweden. The prescription is issued in the doctor's electronic prescribing system and then transmitted through a secure network (Sjunet) to the national e-prescription mailbox at Apoteket AB. Only the prescribing physicians and Apoteket AB's pharmacy personnel have access to the prescription. The patients can then get their medication dispensed at any pharmacy in Sweden.
http://www.e-receptstockholm.se/imcms/servlet/GetDoc?meta_id=1008
The Prescription Register Act (SFS 1996:1156, *lag om receptregister*) stipulates the conditions for Apoteket AB to keep a register and the accepted purposes for the processing of personal data. The Act corresponds to the general principles of data protection.
The Regulation on prescription and delivery of medicine (*Läkemedelsverkets föreskrifter om förordnande och utlämnande av läkemedel m.m. (receptföreskrifter); 1997:10*)[15] stipulates the requirements for prescriptions, both paper-based as well as electronic prescriptions. It includes specific rules concerning electronic prescriptions as well as telephone prescriptions. According to Section 35 an electronic prescription is only possible if the care provider and the pharamacy have concluded a written agreement. The agreement has to contain rules on a secure and accurate transfer of data between the care provider and the pharmacy.

[15] Available in Swedish at http://www.lakemedelsverket.se/upload/lvfs/konsoliderade/LVFS1997_10%20omtryck.pdf

9 General assessment

The Swedish regulatory framework has recently been amended in order to correspond to the increasing need for exchange and transfer of personal health data between care providers and also allowing patients to access their own health information. In addition, the already existing legislation stipulates detailed rules on the professional secrecy of physicians. Therefore, from a legal point of view, no major obstacles should be expected when new eHealth services are introduced.

Over the past years, the creation of a secure infrastracture as well as the development and implementation of new applications has been one of the main objectives within the national eHealth strategy in Sweden.

Electronic prescriptions are widely used and both the legal as well as the technical framework are well in place. While telemedicine applications are not as widely used yet, several applications are being developed and implemented.

Though the national patient summary has not been fully implemented yet, its development is well on its way.

One of the technical and organisational obstacles for Swedish eHealth services might be identity management, which is, however, not limited to the health sector but includes the general question how the present eIDM systems should be further developed. This is also a matter of providing e-government services in general.

With a few minor exceptions, Sweden has come a long way regarding eHealth services, both from a legislative as well as technical-infrastructural point of view. Some minor adjustments might be necessary when it comes to cross-border services, but due to the involvement in several international eHealth projects, the experience gained in these projects might be of great assistance to Sweden even in this regard.

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