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Study on Legal Framework of
Interoperable eHealth in Europe

NATIONAL PROFILE
THE NETHERLANDS

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Directorate General Information Society

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1 Documents

1.1 Applicable Documents

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

1.2 Reference Documents

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

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

2 Glossary

2.1 Definitions

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

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

An overview of the Dutch healthcare system can be found in the Dutch HiT country report published by the European Observatory on Health Systems in 2004.
http://www.euro.who.int/Document/E84949.pdf
A brochure with a summary of the new health insurance system for curative care (introduced in January 2006) is published on the website of the Dutch Ministry of Health, Welfare and Sport:
http://www.minvws.nl/images/boekje-zorgstelsel--engels_tcm20-107938.pdf

From the report and the brochure, we report the following important observations:
"In the Netherlands, the government does not participate directly in the actual provision of care. This is a task principally for the private care suppliers: individual practioners and care institutions."
"The ministry of Health, Welfare and Sport (Ministerie van Volksgezondheid, welzijn en sport, VWS) defines policies that aim to ensure the wellbeing of the population in the Netherlands and that aim to help the populace to lead healthy lives. One of the main objectives is to guarantee access of health care facilities and service of high quality."
"The ministry of Health, Welfare and Sport and local authorities bear joint responsibility for public health care and play separate complementary roles. The ministry of Health, Welfare and Sport runs the National Institute of Public Health and the Environment (a major knowledge centre for public health care) and is, together with the Ministry of Interior and Kingdom relations, also involved in integrated public safety policy."
"Inspectorates monitor and enhance the quality of health and wellbeing of the population. There are three inspectorates: The Food and Consumer Product Safety Authority (Voedsel- en Waren Autoriteit, VWA); the Health Care Inspectorate (Inspectie voor Gezondheidszorg, IGZ); and the Inspectorate for Youth Care (Inspectie Jeugdzorg, IJZ). In the field of health care, the Health Care Inspectorate is the most important."
"In the Netherlands, three parallel compartments of insurance coexist:

- The first covers long-term care and the so-called 'uninsurable' medical risks. The care in this compartment is largely provided and funded by the state via the Exceptional Medical Expenses Act (AWBZ).
- The second covers short-term medical care (cure) which should be universally accessible. The care in this compartment is provided and funded by the state and the insurers.
- The third covers the care that is not included in the first or second compartment and for which everyone can voluntarily insure themselves; typical examples are dental treatment and alternative medicine.

These three compartments characterize the organizational structure of the Dutch healthcare system."
"The ageing population will intensify the pressure on the Dutch healthcare system. More and more people will develop chronic conditions such as diabetes, cardio-vascular disease and bronchial complaints. The accessibility, affordability and quality of the care must continue to

be guaranteed. It is for this reason that the New Health Insurance Act was introduced in January 2006."
"The new health insurance system was implemented following decades of discussions. It is a balance between a solid basis and the dynamics of the market. A care system in which the patient – the insured party – occupies centre stage.
The key elements of the new act are:

- A new standard insurance for all;
- Citizens can change insurer every year;
- Insurers compete for the business of the insured;
- Customers and insures stimulate suppliers to provide better quality;
- Compensation for people on low incomes"

"The system is of a private character, with public limiting conditions. The government, for instance, has stipulated that everyone in the Netherlands is obliged to take out insurance; anyone who fails to do so, will be fined. Health insurers are obliged to accept everyone, irrespective of age, gender, state of health. The government no longer arranges everything. Parties in the market have greater freedom and responsibilities to compete for the business of the insured. Care providers will have to pay greater attention to their performance and can supply more tailor-made care for their customers. The patient/client occupies a central role, with more opportunities but also more responsibility. It is up to the patient/client to bring about improvements to the quality. A well-informed patient can single out the provider that offers the best care for his condition. This will spur healthcare providers (doctors, hospital boards, etc.) to raise their performance. Medical insurers will bear more responsibility for matching the demands of the consumer with the offerings of the providers. The government remains responsible for the accessibility, affordability and quality of health care."

3.2 Use of ICT in the Dutch healthcare sector

There are no recent and reliable data on the use of ICT by Netherlands specialists, hospitals or pharmacies. A recent (2007) status of the use of ICT by general practitioners in the Netherlands 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 Dutch country brief, we take over the following key findings:
"The Netherlands can be regarded as one of the European frontrunners in e-Health use among General Practitioners. In areas of "use of local and networked EHR's", "exchange of administrative patient data", and "computer use in consultation", the Dutch usage rates are well above the averages found in the EU27 Member States, Iceland and Norway.
With respect to infrastructure, 99% of the Dutch GP practices use a computer, 97% of the practises are connected to Internet and 82% of these GP practises use a broadband connection. In the Netherlands, the use of electronic networks for the transmission of medical patient data is well established and widespread. 84% of GP practises receive analytic results from labs and

still 26% exchange data with other healthcare providers. The Netherlands show exceptionally high usage rates when it comes to the transfer of any kind of medical patient data, as well as with regard to the transfer of administrative patient data. Especially remarkable is the high occurrence of ePrescribing which is used by 71% of the practises.
The storage of electronic patient data is common practice in the Netherlands. All types of medical patient data are stored in digital form in more than 90% of the GP practises and 97% of the Dutch GP practises register at least one type of patient data. The only exception is the storage of radiological images. These are registered in 43% of GP practises, a percentage that is still above the EU27 average of 34%. Medicamentations, diagnoses and symptoms are registered most often (97, and 96% of EHR-using practises).
In the Netherlands 37% of the practises use coded data only for the storage of electronic patient data. This share is significantly above the EU27 average of only 27%. For most security features, the Netherlands show scores that roughly correspond to he EU27 averages. An exception is the use of e-signatures which is more common in the Netherlands than in EU27 average (28% vs. 19%).
94% of the GPs in the Netherlands uses a computer in a consultation with patients. This positions the Netherlands clearly above the EU27 average score of 66%. The computer can be used to display patient's file, provide supporting information when making treatment or medication decisions, but also for the explanation of medical issues to the patient, e.g. by means of a graph, photo or animation."

3.3 National eHealth strategy

An overview of the Dutch eHealth strategy can be found in the October 2007 ERA Report "eHealth strategy and implementation activities in the Netherlands" (Authors: Hans Haveman, Ministry Health, Welfare and Sport, Chris Flim, NICTIZ) and a Report of the Dutch Ministry of Health, Welfare and Sport "ICT in the Dutch Healthcare: An international Perspective" of May 2006.
http://www.ehealth-era.org/database/documents/ERA_Reports/eHealth-ERA_Report_Netherlands_03-10-07_final.pdf

http://www.minvws.nl/en/reports/ibe/2006/ict-in-dutch-health-care-an-international-perspective.asp

For our Study, the following observations, adapted from these reports, are important:
"The primary aim of the Dutch government's IT policy for the health care sector is to improve affordability, access and quality by creating preconditions for an optimum and safe usage of ICT. The introduction of the Electronic Health Record (EHR) with corresponding infrastructure will function as a lever for other ICT applications in health care (e.g. Telemedicine)."

"The Ministry of Health, Welfare and Sport works with the National IT Institute for Healthcare (NICTIZ)[1] and the Central Information Point for Healthcare Professions (CIBG)[2] on the development of a national infrastructure and a nationwide system for the EHR. However, the promotion of ICT in healthcare does not stop at the geographical borders of the Netherlands. Many initiatives have also been launched in the international domain, aimed at improving the affordability, accessibility and quality of healthcare through the deployment of ICT (e.g. Large Scale Projects, SNOMED, sustainable Telemedicine)."

eHealth infrastructure (AORTA)

"The Dutch Ministry of Health, Welfare and Sport also works with the players in the health care sector to build a nationwide system for the safe and reliable electronic exchange of medical data. This national infrastructure for healthcare (called AORTA) consists of several components such as (i) a national registration system for identification and authentication of patients, healthcare providers, insurers and other care agencies, and (ii) a National Switch Point (LSP) which provides a reference index for routing, identification, authentication, authorization and logging. This LSP can be compared to a traffic-control tower which regulates the exchange of patient data between the healthcare providers."

Electronic Health Record

"One of the primary aims of the Dutch government's IT policy for the health care sector is to improve affordability, access and quality by creating a climate which is conducive to optimal and secure use of IT. The government intends to achieve this by the nationwide implementation of an EHR and the requisite IT infrastructure."

"The EHR is a virtual record, comprising a set of applications which are connected to the national infrastructure, AORTA. Data from different health care information systems are linked in the EHR. Authorized care providers can consult these data to obtain a clear picture of a patient's medical history or medication use. The digital exchange between health care providers takes place via the AORTA model, an architecture consisting of different components, including the Citizen Service Number (BSN), the Unique Healthcare Provider Identification (UZI), the National Switch Point (LSP) and the information systems used by the health care providers. Together these components form the 'chain of trust' in which medical data can be safely shared."

"The government has opted to deploy the EHR gradually and started by the launch of an Electronic Medication Record (EMD) and a Patient Summary Record for the Locum GP (WDH), a record for the general practitioner who is in service evenings and in the weekend. Many other applications, chapters of the EHR, are in the pipeline."

[1] The NICTIZ is a neutral and independent organization which was founded in 2002 by various players in the healthcare sector. It is responsible for the design and construction of the nationwide basic infrastructure and for the development of standards for an Electronic Health Record. For more information see www.nictiz.nl.

[2] The CIBG (www.cibg.nl) consists of nine different units and is an executive arm of the Ministry of Health, Welfare & Sport. The registration of data and the provision of information are among its most important tasks. Each unit specializes in a specific segment of the care market.

"The Dutch program "patient access to the EHR" will give patient the possibility to view its own medical data. Through the patient access the patient gets more control over his own care and health. In the future, the patient can add, change, delete data in a personal health record."

Identification and authorization
"For the purposes of identification and authentications the Dutch government introduced the Citizen Service Number (BSN) for patients and the Unique Healthcare Provider Identification (UZI) for health care providers. The BSN makes patients uniquely identifiable in electronic transmission. The composition and amount of the numbers are the same as the current social security number (so-called sofi number). Healthcare providers can look up and check out the BSN via the care sector message service (SBV-Z)".

ePrescription
"The Dutch Ministry of Health strives to a more flexible process and a more customer friendly design of the recipes traffic with less (administrative) burdens for those involved: prescribing physician, pharmacist and citizen. Digital recipes traffic - both for first recipes as for repeated recipes - has the future and has been implemented at several locations. The operational management of a prescribing physician and a pharmacist become much more efficient."
The further change to digital recipes traffic is helped by the introduction of a digital sign for physicians (through the new Medicine Act), the BSN and the EHR.

Health cards
"The Netherlands introduced on 1 January 2006 the Electronic Health Insurance Card. Insured people get automatically or if not can ask these card form the insurance companies. The Netherlands is playing an active role in the debate on the electronic insurance card which the EU plans to introduce in 2008. Nevertheless patients will not be able to use the European insurance card, to access their own records. In care the electronic access of citizens to their EHR-data, should be done through a safe and secure connection. On the issue of patient access to their own medical records the Dutch are focusing on the electronic national identity card which will be introduced in 2008/2009."

Other applications
"The introduction of the EHR will function as a lever for other ICT applications (e.g. telemedicine). There is no separated formulation of a national telemedicine strategy. There are a lot of services, pilots and programs from which telemedicine is a part. In the coalition program there is foreseen in a program Innovation in the care."

3.4 Regulatory framework for patients' summaries

At this moment the Netherlands doesn't have legal provisions in the area of patients' summaries.

However, in May this year the Minister of Health introduced a change in the law for the use of the BSN with respect to the electronic exchange of information in the health care (Wijziging van de Wet gebruik burgerservicenummer in de zorg in verband met de elektronische informatieuitwisseling in de zorg).
http://www.infoepd.nl/informatiepunt_com/actueel_wetsvoorstel_landelijk_epd_in_tweede_kamer.php
http://parlando.sdu.nl/cgi/login/anonymous
The aim of this legislation is to address issues, such as security, data quality, authorization and access (by the patient amongst others), standardization and the actual use of Electronic Health Records
Legislation for the nationwide EHR will regulate at the very least:
• (mandatory) connection of health care providers with the National Switch Point;
• electronic availability of patient data via the National Switch Point;
• safe and reliable information exchange via the National Switch Point.
This National Switch Point is the crucial and indispensable hub for all electronic data exchange for the EHR. This LSP will allow the medical data to be retrieved from one healthcare provider by another, but only by professionals in the field, as determined in the BIG Act, who also have a treatment relationship. The patients themselves will of course also be able to inspect their data.

There will soon be a legal definition of how the availability of relevant data must be handled and what the norms and standards are for the protection of privacy when data is exchanged electronically. In order to prevent misuse of medical data, the legislative amendment pays attention expressly to the protection of privacy. The act therefore also contains sanctions in the event of the data being misused.

3.5 Regulatory framework for telemedicine

There are no specific legislation in the Netherlands with regard to telemedicine. However, the Royal Dutch Medical Association (KNMG) introduces a guideline for doctor-patient contact in 2005. Last year this guideline is reviewed and in January this year the revised guideline came into force.
http://knmg.artsennet.nl/uri/?uri=AMGATE_6059_100_TICH_R203914374226695
http://knmg.artsennet.nl/content/articles/9846/AMGATE_6059_100_TICH_R203725209739046/

From this guideline and the press release, we take over the following key findings:

The guideline for doctor-patient contact addresses the question of the conditions under which doctors may treat patients through the Internet. The key change with respect to the old guideline is that

prescribing medication over the Internet for patients who you do not know is no longer allowed, as a result of a change in the new Medicines Act.

The guideline is applicable to all contact between doctor and patient that takes place over the Internet and in which an agreement for treatment is initiated or continued. The guideline is however restricted to three types of contact:

- contact in which the doctor gives a patient advice for a specific situation
- contacts in which the doctor commences pharmacotherapy
- contacts in which the doctor gives repeat prescriptions

The guideline is not applicable in other cases.

The basic principle is that care is required when the Internet is used, in the interests of the quality and continuity of the care provided for the patient. Medication may only be prescribed online if there is a pre-existing doctor-patient relationship, i.e. if the doctor knows the patient, has seen him and has the medication history available. Additionally, the doctor must have a reliable medical file before he prescribes medication online.

There must also be a pre-existing relationship involving treatment if a doctor is to provide a patient with advice over the Internet about medical matters. This can only be otherwise if the risks associated with the online advice are minimised. Whether or not that is the case will depend on the type of contact and the type of treatment and will have to be assessed by the doctor.

In addition to these general principles, the guideline contains a number of requirements for taking care during online contact. The guideline also discusses the responsibilities of the patient and gives them information about the way the doctor will be working.

3.6 Regulatory framework for electronic prescriptions

In July 2007, the new Medicines Act (Geneesmiddelenwet) came into effect. This new act introduced a ban on the prescription of medications over the Internet to persons whom the prescribing physician has never met in person, or who the prescriber does not known or from who the prescriber does not have a medical history available.

In view of this ban, the KNMG changed its guideline and ruled that prescribing medication over the Internet for patients who you do not know is no longer allowed.

3.7 Overview of relevant legislation

For this study the following regulation and legislation is relevant:

- Health Insurance Act
- Medicines Act
- The Guideline for doctor-patient contact of the KNMG (September 2007).
- Act Use of the Citizen Service Number in the Health Care (10 April 2008)

- Change in the law for the use of the BSN with respect to the electronic exchange of information in the health care (May 2008)
- Professionals in Individual Health Care Act
- Medical Treat Agreement Act
- Personal Data Protection Act

4 Regulatory framework for the healthcare profession

An overview of the regulatory framework for the medical profession in the Netherlands is presented in the Dutch monograph of the International Encyclopedia of Medical Law (authors: André den Exter, Martin Buijsen, Herbert Hermans):
http://www.ielaws.com/medical.htm
This chapter of our report is largely based on this monograph.

4.1 Legal conditions for the practice of healthcare

Individual Health Care Act

"In 1993 the Professions in Individual Health Care Act (BIG) came into effect. The BIG allows anyone, Dutch or non-Dutch, to practice in the field of individual health care, with the exception of the stipulated restrictions as well as the use of a protected professional or academic title. There are two ways for a non-Dutch graduate to be granted the right to use a protected professional or academic title. First, there is a general rule which has a Ministerial Order decide which foreign diplomas show a level of education equal to the Dutch level. Holders of such diplomas are entitled to register or to use a certain academic title. The Minister may have the validity of diplomas depend on the nationality of the person concerned. In accordance with EU guidelines, diplomas of doctors, dentists, pharmacists, midwives and nurses who are subject of member states of the European Union will be recognized and validated in any case."
"Second, the holder of a foreign diploma, who is not subject to the general rule or whose nationality is not mentioned in the general rule, may request the Minister to recognize his diploma. The Minister may issue a certificate, which indicates that there is no objection to registration as far as the applicant's competence is concerned."
"In the BIG Act, a prohibition of the practice of medicine by others than medical doctors has been replaced by a system of "reserved actions" (medical acts which may only be performed by medical doctors or other groups of designated persons). This list of reserved actions is supposed to describe the most hazardous actions which must be certain to be performed by competent people. As developments in medicine happen in rapid succession, article 37 BIG makes it possible to expand or to change the list of reserved actions by Implementing Regulation (AMvB), provided a Bill has been proposed within six months of the Implementing Regulation (AMvB) if it is to remain valid."
"The reserved actions listed in Article 36 are:

1. surgical treatment
2. obstetric assistance
3. endoscopy
4. catheterization
5. injections
6. punctions
7. anaesthetizing a patient
8. the use of ionizing radiation

9. the employment of elective cardioversion
10. applying defibrillation
11. the employment of electro-convulsive therapy
12. the use lithotripter for medical purposes
13. actions with human reproductive cells and embryos, not aimed at accomplishing a natural pregnancy."

"Doctors are the only medical professionals qualified to perform all reserved actions mentioned, as far as they may reasonably assume themselves to be competent. Besides doctors, dentists and midwives are qualified to person a (certain) number of reserved actions, again as far as they may be deemed competent."

"BIG provides legal recognition and protection of eligible specialist titles, which means that regulations of the professional organizations must be approved by the Minister of Health. Only those who are recognized specialists will be entitled to use the specialist title in question."

"BIG lists the requirements a doctor has to fulfill in order to be registered:

- A doctor must be skilled and must fulfill the educational requirements;
- A doctor will not be registered if he has been struck off on account of a disciplinary measure;
- A doctor will not be registered if he has been placed under legal restraint or if he has been expelled from the profession by a judicial sentence in any other way.

The registration of doctors is periodical."

"Besides the qualification of doctors, dentist and midwives to carry out reserved actions, the BIG act offers other professionals such as nurses the possibility to do so, their qualification being derived from that of the afore-said professionals. The BIG act stipulates a number conditions to allow for this."

"The system of registration and title protection as formulated by the BIG Act assures clients of health care by professionals, complying with legal educational standards when using a title. Whether or not the professional uses a title legitimately can be checked by consulting the registers in question."

The Quality of Health Care Institutions Act

"The Quality of Health Care Institutions Act shows the Dutch government's concern for promoting the quality of health care. Contrary to the BIG Act, this Quality Act does not apply to the individual medical professional but to the health care institutions. These health care institutions must offer care responsibly and ensure that an appropriate organisation is

available for that care, and a systematic quality system for it. These general standards can if necessary be tightened up by Government Degree ("AMvB")."

"The care institution has the additional obligation to draw up an annual quality report. The public health inspectorate has the job of supervising compliance with the requirements."

4.2 Control over the practice of medicine

"In the Dutch health care medical disciplinary rules, besides civil law and criminal law, are important to the individual practice of medicine. The disciplinary rules aim at monitoring and furthering the quality of the actions of those categories of professionals who are subject to them. The BIG act contains disciplinary measures such as (article 48 BIG Act):

- Warning
- Reprimand
- A fine with a maximum of EUR 4.500,-
- Suspension of the practice of medicine / registration
- Disqualification from medical practice
- Partial qualification from practice in the field concerned
- Striking of the register"

"All complaints are initially heard by regional disciplinary tribunals. The Medical Disciplinary Rules allow interested parties, the board of the institution employing the defendant and the Inspector of Public Health to file a complaint with the Medical Disciplinary Tribunal. The BIG Act makes it possible for persons who issued an order to the defendant to file a complaint as well. The BIG Act allows for public sessions of the Tribunals, unless there are important objections (art. 70 BIG)."

"Apart from the Disciplinary Rules which provide for measures for professional reprehensible behavior, the BIG act has the following measures on account of incompetence (article 80):

- Qualification restricted by certain conditions;
- Partial disqualification;
- Striking of the register

A Tribunal for Medical Supervision in the Hague is authorized to enforce these measures. It can do so when the professional cannot be considered able to practice because of his physical or mental health, or because of alcohol or drugs abuse."

4.3 Professional liability

"Medical professionals may be held liable for professional errors under civil law, criminal law and Disciplinary Rules. The general regulation of respectively, civil law, criminal law and Disciplinary Rules apply in cases of professional error, i.e. there are no specific regulations at variance with common law. An exception to this rule is the regulation in the Medical Treat

Agreement Act (WGBO) concerning liability of hospitals in case of an error made by a hospital-employed professional."
"If a doctor causes injury to a patient by his treatment, he may be sued on the grounds of default or tort. Default consist of the failure to fulfill a contract; the patient is assumed to enter into a medical treatment contract with his doctor on the basis of which he can sue the doctor for default at the latter's failure to fulfill the contract (see article 446 WGBO). Pursuant to article 453 WGBO, the 'reasonably competent physician'' is the norm in judging a doctor's actions. This means that a doctor's actions are tested by the actions of a reasonably competent physician in equal circumstances. In judging whether the criterion of 'a reasonably competent physician' has been met, the judgment of experts is of major importance. The obligation a doctor enters into with a patient is usually regarded as an obligation of effort and not as an obligation of a certain result; the result itself need not be guaranteed. "
"Doctors can be attached to a hospital in various ways; they are either employed by the hospital or they are admitted by contract. The matter of attachment to an institution decides the way in which a doctor may be held liable for errors made during the treatment. When a doctor is employed by a hospital, the hospital may be held liable for default and the doctor for tort if an error has been committed. When a doctor works in a hospital on the basis of an admittance contract, problems may arise when an error has been made during the treatment. It may not be clear who entered into a contract with patient concerning, and in what way the hospitals' as well as the doctor's liability has been limited. Article 462 WGBO) introduced a central liability of the hospital/. The hospital may be held liable as 'if it were a party to the contract'. Besides the hospital the doctor remains liable for his own actions all the same."
"Pursuant to article 463 WGBO, medical practitioners and hospital are not entitled to restrict or exonerate their liability for failures / error."
"When a doctor has made a serious professional error, he can be prosecuted by a criminal court on the basis of Article 307 Penal Code (culpable homicide) as well as on the basis of Article 308 Penal Code (grievous bodily harm)."

4.4 Professional secrecy

"Medical professional secrecy is of the utmost importance. It has its legal basis in the nature of the profession."
"Article 457 WGBO lays down the main ruling for doctors, stating a medical practitioner does not provide information about the patient to a third party, nor does he grant access to the patient's record, unless on the grounds of a legal regulation. A third party is not the one whose professional cooperation is necessary to fulfill the contract, such as colleagues who have been consulted."

"Article 458 WGBO contains an important exception to this rule. This article states that a health care professional is allowed to supply information on the patient or allow access to records to a third party without the patient's consent for statistical or scientific research purposes in the field of public healthcare. In this case the request for consent should be either reasonably impossible and the greatest care has been taken to ensure that the patient's privacy

is not violated disproportionally or, the request for permission cannot be reasonably required and the data have been supplied in such a way that the individual patient cannot be traced easily. Moreover, data may only be supplied without consent if:

- The research is of general importance;
- The research cannot be carried out without the data in question;
- The patient concerned does not explicitly object to the supplying of information.

This regulation is meant to prevent scientific research from being hindered unnecessarily, while it also provides sufficient guarantees for the protection of the patient's privacy."

"Professional secrecy has the two components of oath of secrecy and the privilege of non-disclosure. The scope of the oath of secrecy is regulated by Article 272 Penal Code, which defines it as 'any secret a doctor is, or should be, aware of having to keep die to his position, profession or a legal regulation'. The oath of secrecy applies to paramedical professionals and nurses, as well. Generally speaking, the oath of secrecy must be adhered to towards anyone except the patient himself. The basis for the privilege of non-disclosure is found in Article 218, penal Code, under which the doctor has been released, towards a judge, from hi obligation to speak. The oath of secrecy is not absolute: it can be lifted by law. An example is article 2 of the Control of Contagious Diseases and Detection of Causes of Disease Act. Under this act the doctor is obliged to inform the State Inspector of Public Health of the occurrence of certain contagious diseases."

5 Processing of personal health data

5.1 Short overview of personal data protection legal framework

The most important rules for recording and using personal data have been set forth in Personal Data Protection Act (Wbp). This act came into force on 1 September 2001 and implements the provisions of the European Directive 95/46/EC.
http://www.dutchdpa.nl/downloads_wetten/wbp.pdf?refer=true&theme=purple
Generally speaking the Dutch Personal Data Protection Act is very similar to the European directive. Both the European Directive and the WBP are based on the following principles:[3]

- Restriction of purpose
  The processing of personal data is limited to prior specified purposes.
- Quality
  The processed personal data has to be relevant for the registered purpose
- Transparency
  The controller has to provide information to the data subject prior to the processing
- Rights for data subjects
  Such as getting access to the personal data or to request to delete or replace the data.
- Security
  Reasonable, state of the art, security measures has to be taken to protect the personal data.
- Responsibility
  There has to be controller who is responsible for the processing of the data.

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

The fundamental principle of article 8 of Directive 95/46/EC (the processing of special categories of personal data) is laid down in Chapter 2, Paragraph 2 of the Dutch Personal Data Protection Act (WBP).

Pursuant to article 16 WBP it is prohibited to process personal data concerning a person's religion or philosophy of life, race, political persuasion, health and sexual life, or personal data concerning trade union membership, except as otherwise provided in this Section. This prohibition also applies to personal data concerning a person's criminal behavior, or unlawful or objectionable conduct connected with a ban imposed with regard to such conduct.

[3] Tekst en CommentaarTelecommunicatierecht, P.C. Knol, G.J. Zwenne, A.H.J. Schmidt, Kluwer, 2005, p. 433 ev.

According to article 21, paragraph 1, WBP the above mentioned prohibition on processing personal data concerning a person's health does not apply where the processing is carried out by:

a. medical professionals, healthcare institutions or facilities or social services, provided that this is necessary for the proper treatment and care of the data subject, or for the administration of the institution or professional practice concerned;
b. insurance companies as referred to in article 1(1)(h) of the Insurance Supervision Act 1993 (Wet toezicht verzekeringsbedrijf 1993), insurance companies as referred to in Article 1(c) of the Funeral Insurance Supervision Act (Wet toezicht natura-uitvaartverzekeringsbedrijf), and intermediaries and sub-agents as referred to in article 1(b) and (c) of the Insurance Mediation Act (Wet assurantiebemiddelingsbedrijf), provided that this is necessary for:
   1º assessing the risk to be insured by the insurance company and the data subject has not indicated any objection thereto, or
   2º the performance of the insurance agreement;

c. schools, provided that this is necessary with a view to providing special support for pupils or making special arrangements in connection with their state of health;
d. institutions for probation, child protection or guardianship, provided that this is necessary for the performance of their legal duties;
e. Our Minister of Justice, provided that this is necessary in connection with the implementation of prison sentences or detention measures, or
f. administrative bodies, pension funds, employers or institutions working for them, provided that this is necessary for:
   1º. the proper implementation of the provisions of laws, pension regulations or collective agreements which create rights dependent on the state of health of the data subject, or
   2º. the reintegration of or support for workers or persons entitled to benefit in connection with sickness or work incapacity.

Article 21 paragraph 2 WBP states that in the cases referred to under paragraph 1, the data may only be processed by persons subject to an obligation of confidentiality by virtue of office, profession or legal provision, or under an agreement. Where responsible parties personally process data and are not already subject to an obligation of confidentiality by virtue of office, profession or legal provision, they are required to treat the data as confidential, except where they are required by law or in connection with their duties to communicate such data to other parties who are authorized to process such data in accordance with paragraph 1.

Furthermore, the prohibition on processing other personal data, as referred to in article 16, does not apply where this is necessary to supplement the processing of personal data concerning a person's health, as referred to under paragraph 1, sub-paragraph a, with a view to the proper treatment or care of the data subject (article 21, paragraph 3 WBP).

Finally, article 21, paragraph 4 WBP states that personal data concerning inherited characteristics may only be processed, where this processing takes place with respect to the data subject from whom the data concerned have been obtained, unless:
a. a serious medical interest prevails, or
b. the processing is necessary for the purpose of scientific research or statistics.
In the case referred to under sub-paragraph b, Article 23 paragraph l sub-paragraph a and paragraph 2 shall likewise be applicable.

Pursuant to article 23 WBP the prohibition on processing data concerning a person's health does not apply where:
a. this is carried out with the express consent of the data subject;
b. the data have manifestly been made public by the data subject;
c. this is necessary for the establishment, exercise or defense of a right in law;
d. this is necessary to comply with an obligation of international public law, or
e. this is necessary with a view to an important public interest, where appropriate guarantees have been put in place to protect individual privacy and this is provided for by law or else the Data Protection Commission has granted an exemption. When granting an exemption, the Commission can impose rules and restrictions.
2. The prohibition on the processing of personal data referred to in article 16 WBP for the purpose of scientific research or statistics does not apply where:
a. the research serves a public interest,
b. the processing is necessary for the research or statistics concerned,
c. it appears to be impossible or would involve a disproportionate effort to ask for express consent, and
d. sufficient guarantees are provided to ensure that the processing does not adversely affect the individual privacy of the data subject to a disproportionate extent.

3. Processing referred to under (1)(e) must be notified to the European Commission. This notification shall be made by Our Minister concerned where the processing is provided for by law. The Data Protection Commission shall make the notification in the case that it has granted an exemption for the processing.

5.3 Information and access rights of data subjects

The WBP contains general provisions with regard to the information and access rights of data subjects. These provisions implement article 10, 12 and 14 of the Directive.

Pursuant to article 33 WBP the responsible party shall provide the data subject with the following information:

- its identity and the purposes of the processing for which the data are intended;
- more detailed information, where - given the type of data, the circumstances in which they are to be obtained or the use to be made thereof - this is necessary in order to guarantee with respect to the data subject that the processing is carried out in a proper and careful manner,.

The information has to be provided prior to obtaining the said personal data, unless the data subject is already acquainted with this information.

Article 35 states that a data subject has the right, freely and at reasonable intervals, to request a responsible party to inform him as to whether personal data relating to him are being processed. The responsible party shall inform the data subject in writing within four weeks as to whether personal data relating to him are being processed.

In the event that personal are being processed, the responsible party shall provide a full and clear summary of the processed information, a definition of the purpose or purposes of the processing, the data categories to which the processing relates and the recipients or categories of recipients, as well as the available information about the origin of the data.

According to article 36 a person who has been informed about personal data relating to him, may request the responsible party to correct, supplement, delete or block the said data in the event that it is factually inaccurate, incomplete or irrelevant to the purpose or purposes of the processing, or is being processed in any other way which infringes a legal provision. The request shall contain the modifications to be made. The responsible party has to inform the requester in writing within four weeks of receiving the request as to whether and, if so, to what extent, it is complying therewith. A refusal to do so must be accompanied by the reasons. The responsible party must make sure that a decision to correct, supplement, delete or block data is implemented as quickly as possible.

5.4 Other relevant rules regarding personal data protection

Other relevant rules with respect to the protection of personal data can be found in the Medical Treat Agreement Act (WGBO) and the Act Use of the Citizen Service Number in the Health care (BSN-z)

Pursuant to article 454 WGBO health care providers are obliged to keep medical records and to add patiënts' comments on them. Article 457 and 458 provide for specific rules with respect to the protection of the privacy of the patient. Pursuant to article 457 a health care provider is not allowed to inform a third party on patient's data without its consent. Article 458 contains an important exception to this rule.

Article 456 WGBO gives the patient the right to have access to and a transcript of its medical records. The doctors personal work-notes are not open to access or transcript as well as data possibly violating the privacy of a third party.

The Act Use of the Citizen Service Number in the Health care regulates the use of the Citizen Service Number (BSN) in the health care sector. The objective of the use of the BSN is to ensure that the personal data to be processed as part of the provision of care does belong to that client.

6 Rights and duties of healthcare providers and patients

The rights and duties of healthcare providers and patients are regulated in the Medical Treat Agreement Act (WGBO). The description of this Act in the following chapter has been adapted from the Dutch monograph of the International Encyclopedia of Medical Law (authors: André den Exter, Martin Buijsen, Herbert Hermans): http://www.ielaws.com/medical.htm and the Dutch book *Tekst & Commentaar Gezondheidsrecht*, Kluwer 2004 (authors: B. Sluijters, MC.I.H. Biesaart, G.R.J. de Groot, L.E. Kalkman – Bogerd).

6.1 Scope of the law

The WGBO (Dutch Medical Treatment Contracts Act) is the end result of years of efforts to strengthen the patient's position. The legislators have chosen a solution under private law, in the form of a special contract between the care provider and the patient. Given the fact that the WGBO comes under private law, it has been included in volume 7 of the Dutch Civil Code. The new regulation is to be seen as the more general legal regulation of the rights and obligations of patients, in addition to which criminal law will have a further role, whereas the standardisation that the regulation contains will also be important for the application of disciplinary stipulations.

The scope of the WGBO is not restricted to the parties to the agreement. By including an extension stipulation (article 464 of the WGBO), the regulations in principle also cover non-contractual but nevertheless similar relationships. Examples of these are treatments that are medical in nature in the context of legal regulations covering working conditions, social security and social facilities.

6.2 Duty of the patient to co-operate

"Article 452 of the WGBO defines an obligation for the patient. This article stipulates that the patient must give care providers information and must cooperate with them. Patients are expected to make efforts to help insofar as they are able. If the patient is negligent, the consequence may be that he is not able to make any claims against the care providers for shortcomings in the way they have fulfilled their obligations. If the reasons are significant enough, this can also be grounds for the care provider to cancel the contract."

6.3 Right to quality care

The WGBO does not provide for specific provisions with regard to the quality of care. However, article 453 WGBO provide for a norm for judging a doctor's actions . The norm is the "reasonably competent physician''. This means that a doctor's actions are tested by the actions of a reasonably competent physician in equal circumstances.

Specific quality norms for health care institutions are laid down in the "Quality of health care Institutions Act". Pursuant to this Act health care institutions must offer sound care and ensure that an appropriate organisation is available for that care, and a systematic quality system for it. These general standards can if necessary be tightened up by a governmental degree ("AMvB").
The care institution has the additional obligation to draw up an annual quality report. The public health inspectorate has the job of supervising compliance with the requirements.

6.4 Right to free choice

According to the WGBO, the patient has the right to freely choose his doctor and to change that choice. However, the health care insurer may limit this freedom of choice, by stating that the patient may only contract a doctor with who the insurer has entered into an agreement.

6.5 Rights related to information about the state of health

"Article 448 WGBO regulates the medical practitioner's obligation to inform the patient clearly, and if required in writing about the state of health and the nature and purpose of the examination or treatment. Apart from the right to information, article 449 WGBO provides for a right not to know. The medical practitioner is bound by contract to respect this latter right, which has a constitutional basis in the respecting of privacy

6.6 Right to give consent

"Pursuant to article 450 WGBO consent is required for a contract for medical treatment and for the medical treatment itself. Consent once granted does not imply consent to each and every medical action; the separate actions require consent as well".
"The requirement of consent for treatments does not imply that explicit consent has to be asked for each medical action. The doctor can inform a patient explicitly without asking for his explicit consent for the medical action. The doctor may presume consent to have been granted if the medical action itself or its consequences are not major ones, such as the taking of blood during an operation. Presumed consent may also be deducted from a person's behavior. However, a doctor should not presume consent too easily. If he does so, he will have to furnish proof of consent."
"Consent to treatment is a basic principle in health care and serves as the justification of the doctor's intervention. Without it, there is, generally speaking, a situation of maltreatment for which the doctor can be prosecuted. Civil law proceedings are another option to sue the doctor on the ground of e.g. default or tort."

6.7 Rights related to the patient's medical record

"Pursuant to article 456 WGBO the patient has the right to have access to and a transcript of his medical records. The medical practitioner supplies the information he possesses on the patient's request, without any exception of information that might be disadvantageous to the patient. The doctors personal work-notes are not open to access or transcript as well as data possibly violating the privacy of a third party."

6.8 Right to protection of privacy and intimacy

Patients have the right to the protection of their privacy in any medical service, particularly in respect of the information about their health (see also paragraph 4.4 and 5.4). Pursuant to article 459 patients also have a right to the protection of their intimacy. Not other persons than those whose presence is required for the delivery of medical services shall be allowed to observe the medical treatment, without the patient's consent.

6.9 Right to representation in case of incompetence

The WGBO contains rules (article 465) to protect the rights of patients who are legally or factually not capable of exercising their rights as a patient. In the case of minor patients, the patient rights are exercised by the parents asserting authority over the minor or by the patient's guardians. The minor patient will always be informed and his opinion will be weighted.

7 Identity management in the health sector

7.1 Overview

For the purposes of identification and authentication distinction can be made between the Citizen Service Number (BSN) for patients and the Unique Care Providers Identification (UZI) for health care providers.
The BSN makes patients uniquely identifiable in electronic transmission. The composition and amount of the numbers are the same as the current social security (sofi) number. Health care providers can look up and check out the BSN via the Care Sector Message Service (SBV-Z).
Patients need to be assured that their records can only be accessed by the authorized health care provider. Patient privacy is guaranteed by, amongst others, the Unique Care Provider Identification (UZI) card. A health care provider uses this card to report and confirm his identity in the electronic transmissions.

7.2 Citizen Service Number (BSN)

From June this year healthcare practitioners are entitled to use the citizen service numbers in their administration systems. From June 2009, they are obliged to use them.
The citizen service number is identical to the "social security number". This number does not provide any information and vest any right. For several reasons there is no separate number for healthcare: one number is easier, this number is already printed in passports and it has been endorsed by the Data Protection Authority.
All users of the BSN in the healthcare sector must use a reliable BSN and be certain that the number and the data belong to a specific person. Before they start using a patient's BSN, they must therefore comply with two requirements:

1. determining the identity of the patient (identification)
   The healthcare provider, or indication body, must determine the identity of the patient on the first contact with them, using a legally valid identity document. The type and the number of the identity document are recorded in their own administrative system. Identification is not mandatory if there is already a treatment relationship with a patient, but there is a duty to ascertain the identity. This means that the healthcare provider must be sure that he know who the patient is. This may simply be by recognition, if the healthcare provider knows the patient well. This may also be done using a legally valid identity document.
2. determining the correct BSN for the patient
   Healthcare providers, indication bodies or health insurers determine the correct BSN for a specific person by asking for it or verifying it through a reliable source. Two

such sources, for example, are the *Sectorale Berichtenvoorziening in de Zorg* (SBV-Z, information provision for the healthcare sector) and de *Gemeentelijke Basisadministratie persoonsgegevens* (GBA, municipal register). A BSN can also be copied across from another user of the BSN who has already verified the number. If there is any doubt, the BSN should be requested again.
In order to access the SBV-Z data, healthcare providers, indication bodies and health insurers are listed in the registers kept by the ministry of Health, Welfare and Sport. For healthcare providers and indication bodies, there is the *UZI* register (unique care provider ID).

7.3 Unique identification for health care practitioners (UZI)

A description of the Unique identification for health care practitioner is published on the website of the uzi-register:
http://www.uziregister.nl/Images/UZI-folder_per_pagina_engels_tcm38-17238.pdf
From this brochure we report the following important observations:
"The UZI-register is the organization that provides unique identification for healthcare practitioners in the Netherlands. The unique form of identification is provided by the UZI-register to healthcare practitioners in the form of an UZI-card, a kind of electronic passport. The UZI-register processes the application, production and issue of the UZI-card. The UZI-register is part of the Central Agency for Information on Healthcare Professions, an agency of the Dutch Ministry of Health, Welfare and Sports."
"The UZI-card constitutes a key condition for secure electronic communication and consultation of confidential information by healthcare practitioners. The UZI-card looks like a bank pass. It contains the electronic identity of a healthcare practitioner, which is protected against misuse. That is why the UZI-card, just like a bank pass, is provided with a unique pin code."
"Healthcare practitioners can use the UZI-card to provide authentication, to guarantee confidential communication or to add an electronic signature. Authentication is particularly important when the healthcare practitioner requires access to, for example, an information system or website. With the help of an UZI-card healthcare practitioners can provide authentication, meaning they can prove their identity. The UZI-card also certifies that the pass holder is a healthcare provider and indicates whether he or she provides treatment on behalf of a healthcare institution. Owning an UZI-card is nonetheless not in all cases sufficient to automatically gain access to healthcare information. To access healthcare information, authorization must also take place. That means that access must actually be granted. The UZI-card does not say who is entitled to what information, but it does contain details on which basis authority can be granted."
"In addition to authentication, the UZI-card fulfils a function to ensure confidential communication. The confidentiality function of the UZI pass guarantees the sender of the information that it can only be read by the person to whom it is sent, preventing anyone else from reading or changing this information."

"Finally the UZI-card can be used to guarantee irrefutability. That means that a healthcare provider can add an electronic signature to a receipt, reference or contract, for example. The electronic signature that is possible with the UZI-card has the same function and value as a signature on paper. The UZI-register has been certified and registered by the Independent Post & Telecommunications Authority (OPTA) to emit a legal electronic signature."
"Only providers of healthcare are entitled to UZI-cards. The healthcare providers group contains healthcare practitioners and institutions. When registering healthcare institutes, the UZI-register employs the criteria from the Quality of Healthcare Institutions Act. Healthcare practitioners refers to all professional practitioners as intended in Article 3 or Article 34 of the BIG Act."

7.4 Legislation

Act Use of the Citizen Service Number in the Health care
In April this year the Act Use of the Citizen Service Number in the Health care (Wbsn-z) came into force. This act regulates the use of the Citizen Service Number (BSN) in the health care sector.

http://www.infoepd.nl/informatiepunt_sites/objects/5a1b49b4ae10224372d7449ff9554879/stb11610_wet_gebruik_bsn_in_de_zorg.pdf

http://www.infoepd.nl/informatiepunt_sites/objects/7e88f9438f4c32665754248cb545bc36/brief_vws_inwerkingtreding_wbsn_z_epd_versie_m.pdf

The objective of the use of the BSN is to ensure that the personal data to be processed as part of the provision of care does belong to that client.
All users of the BSN in the healthcare sector must use a reliable BSN and be certain that the number and the data belong to a specific person. Before they start using a patient's BSN, they must therefore comply with two requirements:

1. determining the identity of the patient (identification)
2. determining the correct BSN for the patient

The healthcare providers record the client's BSN in their administration when recording the personal data with regard to the provision of care. The healthcare provider always quotes the client's BSN when providing personal details relating to the provision of care, indication for care or insurance for care to the healthcare provider, indication body or health insurer respectively.

Legislation on the Electronic Health Record
In May this year the Minister of Health introduced a change in the law for the use of the BSN with respect to the electronic exchange of information in the health care (Wijziging van de

Wet gebruik burgerservicenummer in de zorg in verband met de elektronische informatieuitwisseling in de zorg).
http://www.infoepd.nl/informatiepunt_com/actueel_wetsvoorstel_landelijk_epd_in_tweede_kamer.php
http://parlando.sdu.nl/cgi/login/anonymous

The aim of this legislation is to address issues, such as security, data quality, authorization and access (by the patient amongst others), standardization and the actual use of the EHR. Legislation for the nationwide EHR will regulate at the very least:
• (mandatory) connection of health care providers with the National Switch Point;
• electronic availability of patient data via the National Switch Point;
• safe and reliable information exchange via the National Switch Point.
This National Switch Point is the crucial and indispensable hub for all electronic data exchange for the EHR. This LSP will allow the medical data to be retrieved from one healthcare provider by another, but only by professionals in the field, as determined in the BIG Act, who also have a treatment relationship. The patients themselves will of course also be able to inspect their data.

There will soon be a legal definition of how the availability of relevant data must be handled and what the norms and standards are for the protection of privacy when data is exchanged electronically. In order to prevent misuse of medical data, the legislative amendment pays attention expressly to the protection of privacy. The act therefore also contains sanctions in the event of the data being misused.

8 Electronic prescription

In July 2007, the new Medicines Act (Geneesmiddelenwet) came into effect. Article 67 of this act introduced a ban on the prescription of medications over the Internet to persons whom the prescribing physician has never met in person, or who the prescriber does not known or for whom the prescriber does not have a medical history available.

The Medicines Evaluations Board (*College ter beoordeling van geneesmiddelen)* classifies medicines into 4 categories:

- prescription-only medicines (class UR)
- medicines that may be provided without a prescription but only at a pharmacy (class UA)
- non-prescription medicines that may only be provided at a pharmacy or under the supervision of a drugstore (class UAD)
- non-prescription medicines that may also be provided outside of pharmacies or sales locations supervised by a drugstore (class AV)

The board draws up a list of the various categories of medicines. This list is updated once a year.

Article 61 stipulates that everyone is forbidden to provide UR or UA medicines, with the exceptions of (i) pharmacists who are carrying out their work in a pharmacy, (ii) General practitioners who possess a special licence and (iii) persons and institutions indicated in ministerial regulations.
Class UR medicines may in principle only be provided by a pharmacist if a prescription is presented. Article 61 paragraph 9 stipulates that this rule may be deviated from in emergencies. The pharmacist does then have to be sufficiently certain that there is no danger of misuse.
The definition of "prescription" (Dutch: *recept*) in the new act takes account of prescribing by means of electronic information carriers. The requirement is imposed on these information carriers that the document is secured in such a way that the prescribing physician issuing it will be recognised on the basis of agreements made with the intended receiving party (pharmacist) as the party with whom such agreements have been made. The document may be signed using an electronic signature. A new aspect of this is that the prescribing physician indicates on the prescription a unique identification of the patient, i.e. distinguishing the patient from other patients in such a way that no confusion is possible.

9 General assessment

The Dutch government has taken major steps over recent times towards the development of the EHR. The introduction of legislation relating to the BSN and the use of this number for the exchange of electronic information has made the actual use of the EPD a possibility. The fear of invasions of privacy due to misuse of the patients' details has delayed the introduction of the EPD over recent years. This still remains a worrying aspect.

The EPD uses the BSN and the UZI register. If a foreign healthcare provider wants access to the data of patients in the EPD, this healthcare provider will have to be listed in the register, in line with the BIG (individual healthcare professions act). Only then can he receive an "UZI pass" and be given access to the EPD.

The introduction of a ban on the prescribing of medicines over the Internet means that the authorities are taking a backward step. The reasons for the ban include previous illegal practices by Internet doctors. The question is whether the ban was really necessary. After all, the guidelines from the KNMG and earlier pronouncements by the Regional Disciplinary Committee for Healthcare in Amsterdam[4] already set clear preconditions and were a good point of departure. Previous pronouncements by the disciplinary committee also indicate that there were already possibilities for taking action against these illegal practices.

It is possible for patients in the Netherlands to make use of foreign healthcare providers. As a consequence of the new Health Insurance Act, parties in the market have a greater freedom and responsibility to compete for business among patients. The patient can single out the healthcare provider that offers the best care for his condition. This provider may also be located in another member state. The medical insurer will bear the responsibility for matching the demands of the patient to the offerings from the providers and is free to decide to give the contract to a healthcare provider in another member state. Of course, the patient is relying on the willingness of medical insurers to contract these foreign providers.

The Dutch WBP (Personal Data Protection Act) is largely based on the European privacy directive. Following on from that directive, the WBP makes a distinction between passing on an individual's data to other countries within the EU and those beyond its borders. Passing data on within the EU is only subject to the standard regulations for the processing of personalised information. This is therefore not an obstacle to the development of cross-border e-Health services.

Linda Eijpe
27 June 2008

[4] Regionaal Tuchtcollege voor de Gezondheidszorg in Amsterdam, 23 January 2007, cases numbers 05/140 and 05/321.
http://www.tuchtcollege-gezondheidszorg.nl/images/05140.asd.pdf
http://www.tuchtcollege-gezondheidszorg.nl/images/05321.asd.pdf

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