



Telemedicine – a legal case study



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Andrienne's Story

A generally health woman wants to manage her wellness, and contacts with *Wellness Partners* for remote monitoring and support. They offer:

- A web based Personal Health Record
- Integration with a physician held Electronic Health Record
- Biosignal collection
- Remote advice and consultation, inc laboratory services, ePrescription and ePharmacy

Her GP supports *Wellness Partners* and himself makes use of a remote second opinion service (*Eurocard*)

The Core Legal Concepts in the Case

Personal Information

- Duties of a PHR or EHR provider
- Rights of a patient or consumer
- Data exchange between service providers
- Data Exchange across borders

Liability for Goods

- Product Liability
- Consumer Protection
- Medical Devices

Liability for Services

- eCommerce
- Distance Contracting
- Medical services
- Professional accreditation and liability

Discussion

Personal Information

- Duties of a PHR or EHR provider
- Rights of a patient or consumer
- **EU level legislation**

- Data Exchange across borders
- **National level Legislation**

- Netherlands

- Consumer Protection
- Medical Devices

Services

- eCommerce
- Distance Contracting
- Medical services
- Professional accreditation and liability

The Personal Health record- EU Level Law

Directive 95/46 on Data Protection

- To facilitate Internal Market through free movement of data, through harmonized rules.
- Within a framework of respect for privacy and personal life (ECHR – art 8).
- Provide special protection for sensitive data, including medical data (art 8)
 - informed consent
 - for medical treatment
 - by a healthcare professional

The Personal Health Record- EU Level Law

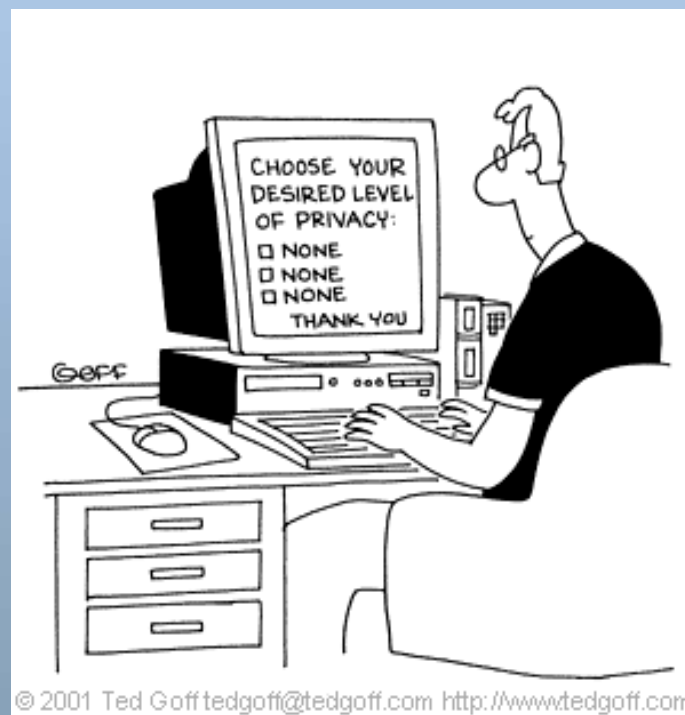
Directive 2002/58 on Privacy and Electronic Communications.

- Security of networks and services
- Confidentiality of communications
- Access to information stored on terminal equipment, processing of traffic and location data,
- Calling line identification,
- Public subscriber directories
- Unsolicited commercial communications.

PHR /EHR - NL Law

Personal Data Protection Act

- Only for specific, explicitly defined and legitimate purposes.
- Appropriate technical and organizational measures
- Sensitive personal data.
- Exemption for medical professionals, if the processing necessary for the proper treatment and care of patient
- Several rights for data subject / patient



PHR /EHR - NL Law

Medical Treatment Act

- Obligation to keep medical records and to add patient's comments on them
- No information to third parties
- Unless the third party is health care provider who is involved in the treatment of the patient
- Rights of patients with respect to medical records

PHR /EHR - NL Law

Act on use of citizen service number in the Healthcare

- From June this year healthcare practitioners have to use the citizen service numbers in their administration systems / medical records
- Before using a patient's BSN, they must comply with two requirements:
 - determining the identity of the patient (identification)
 - determining the correct BSN for the patient

PHR /EHR - NL Law

Future Regulation on EHR

- The aim is to address issues, such as
 - Security,
 - Data quality,
 - Authorization and access (by the patient amongst others),
 - Standardization
 - Actual use of the EHR.
 - Sanctions

The Activity Sensor - use of a medical device

Points from the story

- Adrienne wears a medical device
- She relies on it for self diagnosis
- Dr Bruin accepts data from the device for decision making



The Activity Sensor – EU Level Law

Consumer Protection

Directive 1999/44 on sale of consumer goods

- product must be fit for purpose
- conform to common standards

Directive 2001/95 on general product safety

- must be safe
- risks of proper use must be made clear

Directive 85/374 on liability for defective products

- no fault liability if causal relationship is established

Medical Devices

Directive 93/42 on Active Medical Devices

- must be safe
- accredited with CE mark

(Note 2007/47 - extends MD software for diagnosis etc)

Activity Sensor - NL Law

Consumer Protection / Dutch Civil Code

- Legal Binding
- Conformity / liability

Producer / Dutch Civil Code

- Strict liability for damages resulting from errors

Activity Sensor - NL Law

Medical Devices Act

- Applies to instruments intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring of disease or a physiological process.
- Permits
- Subject to approval
- Government may ban certain products

Healthcare Services via web and phone

Points from the story

- On-line advice
- Call centre advice
- Laboratory testing
- Electronic prescription
- ePharmacy
- Remote second opinion



Services - EU Level Law (I)

Directive 2000/31 on Information Society Services and Electronic Commerce

- Applies to some medical services
- Country of origin principle applies
- For regulated professions - detail of local accreditation, and local applicable rules
- Special rules on contract formation – right to rescind
- Telecoms service provider is a ‘mere conduit’, not liable for the information transmitted

Services - EU Level Law (II)

Directive 1999/93 on electronic signatures

- Electronic signature equal to handwritten, certain rules of security apply.

Directive 1997/7 on distance contracts

- Prior information, written contract, right to rescind
- Member State right to restrict certain trade on basis of public safety

Services - EU Level Law (III)

Directive 2005/36 on Mutual Recognition of professional qualifications

- Applies to doctors, nurses, midwives, dentists pharmacists ...

On-line Pharmacy - Doc Morris Case

- Mail order sale of OTC may not be prohibited
- Mail order sales of POM may be prohibited
- Country of purchaser legislation applies

Directive 2001/83 on medicinal products for human use

- No direct to consumer advertising of POM

Healthcare services - NL Law

Distance contract / E-commerce – Civil Code

- Information obligation
- Right to withdraw
- Limitation of liability for hosting, mere conduit, caching

Healthcare services - NL Law

Guideline for doctor-patient contact

- Royal Dutch Medical Association (KNMG), 2005
- Applicable if contact takes place through internet for:
 - 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

Healthcare services - NL Law

Guideline for doctor-patient contact

- Pre-existing relationship involving treatment
- Requirements with respect to information

Healthcare services - NL Law

New Medicine Act

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



THANK YOU



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