

“Legally eHealth”

Study on Legal and Regulatory Aspects of eHealth

The study on Legal and Regulatory aspects of eHealth aims at contributing to the actions of the eHealth Communication and Action Plan that address the need to establish greater legal certainty in Europe with respect to the practice of eHealth service delivery and the use of eHealth tools within the context of the existing legal framework of relevant EU level legislation.

Objectives of the Study

eHealth is premised on a fundamentally new patient experience that is unconstrained by familiar points of entry to healthcare or traditional channels for delivering information or care. eHealth allows services to be delivered at a distance, outside standard healthcare settings and with a preservation of anonymity or pseudonymity if the patient so wishes. Not surprisingly, therefore, the eHealth revolution has as many serious implications for healthcare regulators and lawyers as well as for medical professionals.

Although policy makers have noted at both European and national level that a lack of legal certainty about the use of eHealth tools and services exists, little has been done to study the issue in detail, to the point that legal barriers are perceived as an obstacle to the deployment of eHealth.

Accordingly the Action Plan proposes that by 2009 the European Commission shall “provide a framework for greater legal certainty of eHealth products and services liability within the context of existing product liability legislation.”

It will establish a baseline report on existing EU level legislation, its impact on the delivery of eHealth and

an analysis of the legal lacunae that may exist.

“Legally eHealth” will deliver this through four key objectives:

- An analysis of the existing EU level legal framework pertaining to the use of eHealth tools, systems and services
- The development of an accessible knowledge base on legal and regulatory aspects of eHealth covering all pertinent EU level legislation and case law.
- The development of a series of case studies to explore and elucidate the practical implications of the identified legislative issues in the use of eHealth tools, systems and services.
- Recommendations on bridging such legislative and regulatory lacunae as may exist.

Study Description

The study uses both traditional legal research methods and the case study method.

The researchers will use standard European legal databases, the records of the European Court of Justice, as well as wider European regulations databases, plus selected national databases.

Scenario

Dr. Jones would like to provide a patient with information specific to his diabetes treatment. She is concerned about ensuring that he accesses the right kinds of information, and also about her own liability and responsibility...

Mr. Breton has developed a tool to track instruments in hospital settings and to link the information to patient data. Before marketing it, he wishes to ensure that the tool fulfils all requirements and criteria on data protection...

Dr. Jones and Mr. Breton can find, in the Legally eHealth database, case vignettes that resemble their situation. Through a series of FAQs, each step of the vignettes is linked to the relevant legal and regulatory questions that arise and how they affect their respective situations. While some questions remain, they now know the parameters of their situation and the issues they will have to address.

“Case vignettes are used to bring to life the complex nature of key legal concepts through the telling of a compelling case story”

In addition to cataloguing and analysing the EU level legal aspects of eHealth, this study explores the extent of their impact on the delivery of healthcare using eHealth tools, systems and services through a series of composite case studies built from a range of real event reports. The case vignettes are used to bring to life the complex nature of key legal concepts such as data protection, data ownership, and product and service liability, through the telling of a compelling case story.

Expected outcomes

The study will analyse the legal framework existing at EU level pertinent to the use of eHealth tools, systems and services. The objective is to explore the wide range of settings in which eHealth tools, systems and services can be used and to map them onto the existing EU level legislation as well as selected examples from Member States level legislation.

To make the concepts readily understandable, case vignettes will be used to examine three main clusters of legal and regulatory issues:

- o Data Protection, confidentiality and security in the context of the collection and sharing of person identifiable data for healthcare and advice;
- o Product and Liability and Consumer Protection in the use of eHealth tools, devices and services in both traditional healthcare delivery; eCommerce and distance contracting (including ePharmacy and advertising).
- o Trade and Competition in the context of using use of eHealth tools in health services planning and delivery in traditional, remote or cross-border healthcare delivery.

Alongside the case vignettes, the study will develop a structured searchable knowledge base covering all the EU level legal, regulatory and policy issues in clusters, which can be explored through practical case. The deliverables will thus provide both an easily updateable knowledge base and a series of case studies that clearly convey the complexities of the practical implications of the regulations.

The study will thus clarify for EU and national policy makers the extent to which existing EU level legislation is sufficient to regulate eHealth, and will highlight any issues that may require legal clarification, or indeed new legal responses.

Finally, based on the research undertaken, the study will develop recommendations on meeting any legislative and regulatory needs that may be found to exist.

“Legally eHealth”

Study on Legal and Regulatory Aspects of eHealth

Tenderer:

European Health Management Association (EHMA) (BE)

Contact person:

Céline Van Doosselaere

Tel: +32 (0)2 502 65 25

Fax:

Email: celine@ehma.org

Website: www.ehma.org

Partners:

- CRID (Centre de Recherches Informatique et Droit), Université de Namur, (BE)
- BASIL Strategies, (FR)

Timetable: from 01/06 to 12/06

Total cost: € 100,000

Study n°:

2005 / S137-135419 (lot 2)

Keywords:

security and privacy, legal aspects of eHealth, regulatory aspects of eHealth, data protection, data ownership, and product and service liability