

eHealth Legal Framework

Study on the Legal Framework for Interoperable eHealth in Europe

eHealth in Europe is mainly regulated by the national laws of the Member States, e.g. with regard to the legal status of the healthcare profession or to the definition of patients' rights but also regarding specific topics such as electronic patient records, telemedicine or ePrescription. The study provides a general overview of these national laws and tries to detect which divergences create the main legal obstacles for interoperable eHealth in Europe.

Objectives of the Study

What are the main legal obstacles for healthcare providers established in one Member State to offer cross-border eHealth services to patients in other Member States? Which national law will determine the rights of patients in this setting? How are Member States starting to regulate electronic patient records, telemedicine or ePrescription? Are new national regulatory initiatives in this field creating new obstacles for interoperable eHealth in Europe?

The Study on the Legal Framework for Interoperable eHealth in Europe aims at providing a general overview of the Member States' legal provisions that are relevant in the context of eHealth, in particular:

- what are the main characteristics of the Member States' *healthcare systems* affecting the introduction of eHealth;
- what is the regulatory framework for the exercise of *healthcare professions*;
- how did Member States transpose the European data protection provisions with regard to *health-related personal data*;
- how do Member States define and implement *patients' rights* and how do divergences in this field affect the provision of eHealth services;
- what is the current legal status of *electronic patient records* in the Member States;
- does the national legal framework of the Member States allow the introduction of *telemedicine*;
- what is the current legal status in the Member States with regard to *ePrescription*.

Study Description and Methodology

The study develops the following theses with regard to the legal framework for interoperable eHealth in Europe:

- The introduction of eHealth in Europe faces important differences between the Member States in the overall organisation of the healthcare sector, in particular with regard to the division of roles between the private and the public sector, financing and reimbursement.
- Most healthcare professions are regulated professions and can only be exercised under strict legal conditions. These conditions can considerably diverge from one Member State to another and can hinder cross-border provision of eHealth services.
- Divergences in the implementation of the European data protection directive, discovered in the course of the 2003 review undertaken by the Commission, continue to exist. Some new divergences have even been added in more recent years.
- The way in which patients' rights are defined and implemented is largely determined by national law and differs from country to country. Moreover there exists no validated European definition of patients' rights.
- Specialised health law doctrine or opinions of medical supervisory authorities frequently express reluctance towards providing care to a patient at a distance but don't necessarily take into account the wide diversity of telemedicine services. This creates uncertainty, in particular in a cross-border context.
- In many Member States the prescription process for pharmaceuticals is still paper-based and the legal framework has not yet been adapted in order to enable ePrescribing.

“The legal complexity in the field of eHealth can, in the current stage, best be tackled by more specific case studies, e.g. starting from currently provided eHealth services – even if they are only provided within the borders of one Member State – in order to examine the specific legal issues that would arise if those services were provided crossing national borders.”

To conduct the study the author relied on a network of national legal experts in the 27 Member States. In addition these experts contacted the key stake-

CASE STUDY

The **Barcelona Telemedicine Clinic (TMC)** is a sub-specialist radiology centre that provides day and night reporting services and support (teleradiology) to client hospitals in Sweden, Spain, the UK and other European countries. In order to remain compliant with the national healthcare laws of the Member States, the clinic needs to work with “national” radiologists. A radiologist working for Swedish hospitals, for example, must be fully registered with the Swedish medical board. For the UK the TMC radiologists must be fully registered with the GMC, or eligible for inclusion on the GMC specialist register, etc.

holders in their country in order to collect all relevant information to draft a reliable country profile on the legal status, plans and trends in the field of eHealth of the Member State. Between May and August 2008 the national experts wrote their national country profile on the basis of a common template. All country profiles were subsequently submitted for review and comments to the national representatives of the i2010 subgroup on eHealth. The country reports are available on the European Commission's eHealth portal website¹. The final study report contains an analysis and assessment of the information provided in the national reports.

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Timetable: from January 2008 to June 2009

Total cost: € 270,000

Study n°: SMART 2007/0059

KEYWORDS

Legal framework, Health law, Interoperability, Telemedicine, Electronic patient records, ePrescription

¹ http://ec.europa.eu/information_society/activities/health/, under "Studies"