



epSOS – legal and regulatory perspectives

epSOS (Smart Open Services for European Patients) focuses on electronic patient record services and operates within a complex policy environment. The initial focus is on cross-border access to Patient Summary data sets and ePrescriptions.

epSOS has been conceived of as a pilot project designed to take place on a large scale, initially involving 12 EU-Member States and expanded to 23 Participating Nations (PN) since 1st of January 2011. The project will demonstrate that - based on European collaboration and the commitment of the Participating Nations - it is possible to improve the quality and safety of healthcare provided to patients outside their country of residence, through sharing of patient health information for the purposes of receiving treatment abroad.

The legal perspective of the epSOS Services

From a Legal and Regulatory (L&R) perspective, it is important to note that the epSOS Services will be offered on a pilot basis. They will be provided in compliance with the EU regulatory framework, and as such will not require changes to national legislation governing the provision of health services. As a pilot, the primary objective of the initiative is to gather information and evidence in order to provide guidance towards full deployment.

The mission of the L&R work area is to ensure that L&R challenges, which are critical to the realization of the epSOS pilots in real life situations, are appropriately recognised and addressed. This work has supported and guided the Participating Nations (PN) in transferring this knowledge to a national level, and has fostered close collaboration with the Data Protection Authorities of all PNs as well as the European Commission. At project level, epSOS is collecting, processing and converting experience from the pilots into practical guidelines on addressing any outstanding issues in the L&R Domain to facilitate progression from pilots to large scale deployment of these services.

A major challenge is the pursuance of synergies with ongoing policy and implementation initiatives in order to ensure convergence of concepts and development. The “Patients’ Rights” Directive 2011/24/EU provides the legal framework for cross border healthcare; epSOS is expected to produce evidence that will support the work and decisions of the Article 14 Voluntary eHealth Network.

The legal analysis

A detailed analysis of the L&R issues related to the epSOS services made it possible to organize the challenges into four main groups relevant to epSOS: data protection and confidentiality; legal issues related to health systems; liability - professional issues and the social context; work protocols, traceability and audit. epSOS has elaborated a set of legal requirements to be integrated in the design and/or the necessary safeguards.

The National Contact Point (NCP) and the Framework Agreement (FWA)

Each PN is represented in epSOS by a National Contact Point (NCP). An epSOS NCP is an organisation legally mandated by the appropriate authority of each PN to act as a bidirectional technical, organisational and legal interface between the existing different national functions and infrastructures.

The NCP is legally competent to contract with other organizations in order to provide the necessary services, which are needed to fulfill the epSOS Use Cases. The epSOS NCP is identifiable in both the epSOS domain and in its national domain. It acts as a communication gateway and also as a mediator for L&R aspects of delivering epSOS Services. As such, an NCP is an active part of the epSOS environment if it is compliant to normative epSOS interfaces in terms of structure, behavior and security policy compliance.

The FWA has been localised in the form of national level contracts in the piloting participating nations which are a pre-requisite to engagement in the pilots. The use of a common Framework Agreement (FWA) blue print as a guideline for national contracts establishes the epSOS Trusted Domain amongst NCPs. This domain is considered to be an extension beyond national or regional territories where epSOS Services are physically provided. Its function is to ensure that epSOS Services can be delivered seamlessly to populations travelling between countries participating in the epSOS Large Scale Pilot. The FWA is used to establish the NCPs, govern the cooperative model of data exchange and form the documented basis for the trusted relationships between parties exchanging rights of patients to data. It also facilitates transparency to ensure that the legal setting of data privacy can be maintained in a crossborder healthcare setting.

At the end of the pilot, the recommendations of the project will hopefully support the process towards a sustainable legal framework for longer-term operational cross-border eHealth services.



Read more: www.epsos.eu

