REGERINGSKANSLIET

Preparatory paper/ memoradum

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A sustainable legal basis for a cross-border exchange of of medical records/sensitive personal data within EU

Annex I Discussion paper Sweden – Finland
Annex II Draft Agreement Sweden – Finland
Annex III Recommendations by the Nordic Legal Network (a short summary)

The Large Scale Project epSOS (epSOS Smart Open Services – Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription) was initiated as an attempt to create a seamless healthcare for European citizens. Key goals were to improve the quality and safety of healthcare for citizens when travelling to another European country. It focused on developing a practical eHealth framework and ICT infrastructure to enable secure access to patient health information among different European healthcare systems. epSOS concentrated on developing systems for the cross-border exchange of ePrescriptions and patient summaries. The time period for LSP epSOS was 1st July 2008 – 30th June 2014. Most of the countries participating in eHN have also been participating members of the Large Scale Pilot epSOS.

The eHealth Network (eHN) has established a subgroup for the upkeep of eHealth cross-border services. At its' 16th June meeting the sub-group decided to continue the work in two different directions:

1) one fast track amendment of the epSOS framework agreement or another simpler form of legal agreement, and
2) a process creating a sustainable legal basis which can also be used for the deployment of eHealth sevices under the Connecting Europe Facility. This legal basis should be discussed in the eHealth Network in November 2014 and adopted May 2015.

Sweden and Finland, who are currently working on creating a system for a permanent exchange of ePrescriptions between the two countries, were given the assignment for bringing forth a preparatory paper proposing recommendations for a sustainable legal basis which

can also be used for the deployment of eHealth Services under the Connecting Europe Facility.

Recommendations to eHN

Sweden and Finland recommends the eHN to use the following strategy for creating a sustainable legal basis for cross-border exchange of medical records/sensitive personal data.

A. Establishing a legal subgroup consisting of lawyers from ministries of participating members with an assignment to deliver a legal multilateral agreement to be signed in May 2015. The work has to be done together with appropriate legal personal at the European Commission.

   It is essential that the group will consist of lawyers from ministries or lawyers from authorities by ministerial delegation. To be able to deliver a legal agreement for signing in May 2015 it is absolutely necessary to ensure that the work done is well within the limits of the national legislations involved. Without this knowledge there will be show-stoppers late in the process.

   The group will also need to work closely with appropriate legal personal at the European Commission.

   The group will further need to have close contact with other professions e.g. technicians and health care professional to ensure that the system created is workable.

   The agreement to be created should be on principles and not on details to avoid constant re-negotiations. All needed details should be set down in annexes with the possibility for re-negotiations for appropriate authorities.

B. The Legal sub-group must start working by the end of November 2015.

   To be able to deliver the document for signing in May 2015 the Legal sub-group needs to start working as soon as possible after the eHN meeting in November 2014.

C. The Legal sub-group should work by the following recommendations.

1. An exchange must have a firm legal foundation. It should therefore be based on EU legislation supplemented with another legally binding document e.g. a multilateral agreement.

The expected participating states are also members of the EU so the legal frame has to be based on EU legislation. However, all subject matters involved are not covered by EU legislation so there is a need for a further legally binding document.

As the legislation for the health area is not harmonized we consider a multilateral agreement between all participating member states to be the easiest and most efficient way forward for creating such a document. An agreement can be created especially for whatever specific needs the participating states may have and also diversified according to different needs the participating states may have.

To avoid the risk of opposing agreements we recommend avoiding using bilateral agreements on this scale of potential participants.

2. A multilateral agreement for a cross-border exchange must specify basic principles as the basis for the exchange to make the system workable within all participating states.

   To make a robust system the participating states have to agree upon a common set of basic principle for the exchange.

3. The agreement has to be based on acceptance of the participating nations' national legislations.

   A system requiring a change of existing legislation cannot come into force in a near future and will probably result in very participants, if any. An exchange based on existing national legislation is the fastest way forward.

4. Patients' consent has to be the basis for the cross-border exchange. Participation in the system should require a *two-stage* consent solution consent, one general consent for participating in the system so medical records can be made available across national borders, and one additional specific consent given at the point of care in an actual health care situation. The patient has to be informed about the cross-border exchange and effects of given consent comprehensively and understandably. As the Patients' rights Directive states when a patient receives cross-border healthcare, it is essential for the patient to know in advance which rules will be applicable. This should help the patient in making an informed choice, avoid misapprehension and misunderstanding and also establish a high level of trust between the patient and the healthcare providers.

   In accordance with the Data Protection Directive 95/46/EC the patients' consent is necessary for an exchange of sensitive personal

data. The article 29 WP in its recommendations to the LSP epSOS also proposed for a two-stage consent solution.

5. The technical solution for the LSP epSOS should be used.

   The system, financed by EU and participating members, was created for the cross-border exchange of personal data during epSOS and succeeded in delivering the asked-for results. The technical solution is in place, in working order and can be used without much delay.

6. The data-exchange is regulated by decided common security- and communication-standards in epSOS and supported by central services and directories.

   The technical solution for the channeling of data used is in reality just an extended service for the national solution. The premise for what can and should be exchanged and disclosed is set forth by the legal framework and the possibilities of prescription solution.

7. The electronic communication has to be encrypted, all transactions logged and the log made available to the subject (patient), either online or by request. All data exchanged in the system must be validated.

   These requirements are essential for the security of the exchange and also to make the system trustworthy for the patients.

8. A common semantic system is necessary.

   As there is no common semantic code in place the epSOS' semantic engine must be considered. This will also include matters of liability in regards to the translation and use of such an engine. The chosen language and code must be able to be communicated between the countries.

9. A system for validation and authentication of participating personal is necessary.

   A common system for matters of security is necessary. A system for audit is necessary but the system used may be within the national audit systems used by the participating states. For the sake of trust in the different national solutions used the agreement need to set basic standards to be used.

10. A common system for the identification of patients is necessary.

A common system for matters of security is necessary, see no. 9 above

11. All data-exchange has to be channeled through secure legal entities.
The system of National Contact Points (NCP) in epSOS architecture should be used with only one NCP for eHealth (NCPeH) in each participating country.

    It is essential to create secure channels for the exchange of health information. The system created in epSOS with one NCP per participating nation minimizes the amount of systems and personal involved and further for control reasons.

12. The NCPeH have to be a legal entity, either separate or part of another entity appointed by the participating state for the upholding of the specific function. The NCPeH should have a control-function to ensure that only valid sensitive personal data are made available across national borders and that only authorized personnel can access the data. The legal responsibility (liability for handling data) can be in the same establishment (legal entity) responsible for the prescription solution and for the NCPeH.

    As the NCPeH is the channel for cross-border data it will make the system easier to manage if the NCP holds most of the functions involved which are necessary to make the system work. This recommendation has to be optional as some of the proposals may not be in accordance with national legislation.

13. The NCPeH should, if in accordance with national legislation be the data controller for data within the borders of its' own country.

    As stated above, no. 8 it is preferable to have the NCPeH manage as many functions as possible to keep the system running as smooth as possible, but it has to be in accordance with national legislation.

14. Liability and jurisdiction between countries will depend on where the wrongful act resulting in harm for a patient was either done or occurred. A transmission of data should be formally accepted by the NCPeH/B thus avoiding some possible uncertainties in the transmission and forum shopping.

    In cross-border situations, the exchange itself creates situations that complicate the responsibilities. The main principles of liability can be described through some examples:

- *Liability for the creating a medical record which is used for health care lies within the jurisdiction of country , e.g. the liability for the proper prescribing of medications. Medications prescribed in country A for a patient from country A and dispensed in country B means that the liability for prescribing the medicine also lies within the jurisdiction of country A. The liability for prescribing in this case lies within the jurisdiction of country A.*
- *Liability for transfer/exchange: Country A is responsible for data content (data integrity) to the NCPeH in country B. If data is changed / modified during this phase then country A is responsible. In practical terms it can be a challenge to identify where the transmission the data has changed. Logging can provide remedy. Two possible solutions are either to allow forum shopping or to make the NCPeH/B acceptance of the transmission formally connected to the transition from one jurisdiction to the other.*
- *Liability for translation: The original prescription is always available as a PDF in epSOS. This is meant to reduce the risk related to translation. The same method of having the original text available should, if possible be used for medical records. Each country is responsible for the translation from a common language (English) and from its' own language to the common language (English).*
- *Liability for dispensing/health care: an error caused by the pharmacy falls within the liability rules in country B (where the action takes place). All participating countries have to consider whether existing insurance-schemes cover foreign nationals who receive medicine prescribed on prescription from country B from a pharmacy in country A, or in an equivalent healthcare situation.*

15. In transmission the NCPeH/A is responsible that the data sent from country A is also in accordance with all legal requirements to be applied in country A.

16. In transmission of personal data the NCPeH/B has to make a formal acceptance of the received data. The formal acceptance specifies the transition from the jurisdiction of the delivering country to the jurisdiction of the receiving country.

    To minimize the uncertainty of which jurisdiction is applicable during the different phases of transmission a system of formal acceptance by NCPeH/B of the transmitted data should be used, thereby specifying the moment of transition from jurisdiction A to B. Until the NCPeH/B has formally accepted the transmission the NCPeH/A is legally responsible for the transmission. This also complies with the recommendation by *The Article 29* WP working

document on the epSOS project ("*Working Document 01/2012 on epSOS* (WP189)) stating that the NCP in country A should be responsible for the *delivery* of patient data and the NCP in country B should be responsible for *retrieval* of patient data.

Forum shopping for patient should not be allowed as such a system may not be applicable in several countries.

17. Participating states have to recognize and fully accept formal requirements used by another participating state in the cross-border exchange.

    In accepting a transmission of medical records the anticipating states have to recognize the formal requirements of another participating state. Formal requirements for e.g. ePrescriptions, prescribing physician, pharmacies, pharmacy personnel, special drugs may vary between participating states. Principally, the formal requirements for e.g. a valid ePrescription must be harmonized for the solution to be effective and put to use. It is however probably not necessary that all formal requirements are harmonized to achieve a common cross-border solution. In a common solution all prescription must be valid but what makes a prescription valid does not necessarily need be identical (harmonized) in all countries. There will however be a presumption that there are no formal obstacles to counteract validity in other countries. Related and relevant is that it is also a conceivable solution where each country in addition has prescriptions that can only be dispensed/transmitted in the issuing country.

18. An emergency override should be considered.

    In cases when the data subject is physically or legally incapable of giving his consent there is a need to make exceptions to the requirement for consent.

19. Matters related to *reimbursement* should not be part of the exchange.

    The matter is financially, legally and technically complicated to solve. To allow for reimbursement at this stage will probably be a show-stopper. The possibility to apply for reimbursement from the patients' country of affiliation is for each country to decide upon e.g. in accordance with the Patients' rights directive 2011/24/EU when applicable.

The Finland - Sweden solution

The recommendations stated above are partly based on the knowledge we acquired during our current work for a permanent cross-border solution of ePrescriptions between Sweden and Finland and the work we've been involved in for a common Nordic cross-border exchange of ePrescriptions done by the Nordic Legal Network. There are no major objections to use the same principles for an exchange in EU, but there are some differences which have to be taken into account when creating a system that will be applicable for the entire EU community.

Finland and Sweden have decided to continue the cross-border exchange of ePrescription begun during the LSP epSOS. The two states are currently working towards a permanent solution for the exchange of ePrescriptions on a full nationwide scale. The intention is to start the exchange during early 2015. The exchange may in time extend also to a permanent solution for the cross-border exchange of patient summaries (medical records). The Swedish-Finnish solution will continue using the epSOS technical solution and also adopt the basic epSOS architecture with one NCP per country as the channel for the data flow between the countries as this is believed to help ease several legal challenges for cross-border exchange. The epSOS legal framework on the other hand is considered inadequate for use beyond the pilot phase. The legal challenges will be solved by a bilateral agreement. For details on this work, see annex I. The current draft on the bilateral Agreement between Finland and Sweden is also enclosed, see annex II.

The Nordic solution

The populations of the Nordic countries travel a lot between the Nordic countries, both for pleasure, work and studies. There are also a lot of people working for longer or shorter periods of time in another Nordic country than the country of affiliation. The need for an established system for a cross-border exchange of sensitive personal data for medical reasons is apparent. As the Nordic countries consist of both EU-members and non-EU-members a cross-border exchange of sensitive data within the Nordic countries cannot rely entirely on a system created for the EU. The Nordic Council of Ministers has therefore established an eHealth group to work for a stable cross-border exchange of health data. The Nordic Legal Network, sub-group to the eHealth group, has been working since September 2012 to analyze and create legal bases for a cross-border solution. A short summary of its recommendations are enclosed, see annex III.