

7 November 2016

**10<sup>TH</sup> EHEALTH NETWORK 21 NOVEMBER 2016, BRUSSELS**

**EXPLANATORY NOTE BY THE JASEHN TASK 6.2 DRAFTING TEAM**

**Topic 4: Legal Agreement on the cross-border exchange of health data**

The Legal Agreement sets out the relevant legal framework comprised of EU law and national laws, and refers to all organisational, semantic and technical criteria as agreed by the eHealth Network and to be adhered to by the Contracting Parties in order to enable the safe and secure exchange of information in the relevant use cases of Cross-Border eHealth Information Services, namely Patient Summary and e-Prescription as well as possible further services as agreed by the eHealth Network.

The enclosed draft versions 2 of the Agreement and the Guidance on Data Protection consider the discussions of Member States' representatives that took place on 11 and 12 October and written comments received by 14 October. Later and future comments by Member States will be considered in the next draft versions to be elaborated and negotiated after this meeting of the eHealth Network, before the foreseen adoption of the Agreement by the 11<sup>th</sup> eHealth Network in May 2017.

Whereas all main elements of the Agreement will be presented during the meeting, the following issues were identified by the drafting team as especially relevant for discussion and further guidance by the eHealth Network.

Nature of the Agreement and its Contracting Parties

In order to avoid time-consuming ratification procedures at national level, the content of the Agreement as well as the definition of the "National Authorities responsible for National Contact Points for eHealth" as Contracting Parties are designed and formulated as broad and general as possible, thus keeping any interference with national law at a minimum. However, the nature of the Agreement must be assessed by each Contracting Party under its own constitutional laws and procedures, which thus might even have different outcomes for different Contracting Parties. Therefore, possibly remaining formal constraints in some Member States seem to be outside the control of the drafting team.

A special issue occurred due to the possible provision of "core services" by the European Commission. The architecture of the eHealth Digital Service Infrastructure is still not decided but pending a decision by the CEF Governance Bodies. The drafting team is currently about to explore which core services bear the risk of possible errors leading to the harm of patient safety and thus liability, and also which core services are a prerequisite for the proper functioning of "generic services" to be provided under the responsibility of Member States. There is probably a need to include the European Commission (Solution Provider) in the contractual obligations, but it is not clear yet in which form since this depends on decisions to be taken at a higher level.

Identification and authentication of patients, health professionals and healthcare providers

The variety of systems for identification used in Member States comprises (a.) electronic means that will be notified under (eIDAS-)Regulation 2014/910/EU and applicable to the health domain, (b.) electronic means such notified but not applicable to the health domain,

(c.) electronic means not notified under Regulation 2014/910/EU, but also – regarding the majority of Member States – (d.) non-electronic means of identification.

Even though Regulation 2014/910/EU covers electronic identification, there is still no solution for the health domain and in particular no agreement on levels of assurance (see the next topic 5 in the meeting agenda).

With regard to the variety of systems used in Member States, it seems unlikely to agree on any common solution for the health domain including mutual recognition beyond Regulation 2014/910/EU, without interfering with some Contracting Parties' national law or their technical prerequisites. Given the use of non-electronic means of identification in the majority of Member States, the drafting team proposes to require no "unique" but the "unambiguous" identification in order to allow the participation of as many Contracting Parties as possible.

#### Governance of the Agreement and its Annex

The Governance of the Agreement and its Annex is closely linked to the CEF Governance Model. Therefore, the signature of the Agreement by the Contracting Parties should constitute one criterion for their admission by the eHealth Network to enter into the operational phase ("go live") with their Cross-Border eHealth Information Services. Furthermore, the aim is to avoid the creation of parallel structures while at the same time the sustainability of the Agreement and the equal treatment of all Contracting Parties must be ensured.

However, the CEF Governance Model does not satisfy all specific needs for the Governance of the Agreement. Whereas the Agreement shall be open also for Contracting Parties in Member States of EFTA with same rights as Contracting Parties from Member States of the EU, this is not reflected in the eHealth Network and other CEF Governance Bodies. Furthermore, not all Members of the eHealth Network will – at least not at the same time – be Contracting Parties to the Agreement. And moreover, some designated Contracting Parties expressed their concern about the possibility of majority votes as foreseen in the Rules of Procedures of the eHealth Network.

Once the revised CEF Governance Model is adopted by the eHealth Network, the drafting team can continue its work on the Governance of the Agreement. With regard to the mentioned specific needs, the drafting team considers proposing the creation of a legal sub-group to the eHealth Network, composed of the Contracting Parties to the Agreement and with its specific Rules of Procedures.