

Non paper
eHealth Network

Disclaimer: This text has not been adopted or endorsed by the European Commission. It contains a synthesis of views collected and may not, in any circumstances, be regarded as stating an official position of the Commission. The information is intended only for the entities to which it is addressed for discussion and may contain confidential and/or privileged material.

Article 14(1) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare¹ assigned the Union to support and facilitate cooperation and the exchange of information among Member States working within a voluntary network (the 'eHealth Network') connecting national authorities responsible for eHealth designated by the Member States.

In accordance with Article 14(3) of Directive 2011/24/EU, the Commission has an obligation to adopt the necessary rules for the establishment, management and transparent functioning of the eHealth Network.

Commission Implementing Decision (EU) 2011/890² establishes the rules for establishment, the management and the functioning of the eHealth Network.

Article 14(2) of Directive 2011/24/EU mandates the eHealth Network to work on interoperability of eHealth systems, to draw up guidelines on effective methods for enabling the use of medical information for enhancement of continuity of care, and to support the work of Member States aimed to develop common identification and authentication measures facilitating transferability of data in cross-border healthcare.

In order to ensure the fulfilment of the objectives indicated in Article 14(2) of Directive 2011/24/EU, the eHealth Network tasks and functions should reflect these purposes.

Electronic communication is a suitable means of rapid and reliable exchange of data between Member States participating in the eHealth Network. In this area, certain significant developments took place and should be reflected into the activities carried out by the eHealth Network.

In order to facilitate the interoperability of eHealth systems, the eHealth Digital Service Infrastructure was developed as a voluntary tool by the eHealth Network and the Commission under the Connecting Europe Facility programme³. The eHealth Digital Service Infrastructure aims to support Member States in setting up cross-border eHealth services, to exchange patient data from ePrescriptions and Patient Summaries and, in the longer run, from electronic health records, but also to develop other use cases. The importance of the eHealth Digital Service Infrastructure in enabling cross-border exchange of health data within the EU to ensure the continuity of care also across borders is also recognised in the 2017 Council Conclusions on Health in the Digital Society⁴.

¹ OJ L 88, 4.4.2011, p. 45.

² OJ L 344, 28.12.2011, p. 48.

³ Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010 (OJ L 348, 20.12.2013, p. 129).

⁴ Council conclusions on Health in the Digital Society making progress in data - driven innovation in the field of health, paragraph 24

The eHealth Digital Service Infrastructure is composed of core services and generic services. The core services are owned, deployed and maintained by the European Commission. They enable and sustain trans-European connectivity. The generic services are owned, deployed and maintained by each of the Member States who sets up National Contact Points for eHealth. The National Contact Points for eHealth, through the generic services, aim at linking the national infrastructure with the core service platforms.

As stressed in the Commission Communication of 25 April 2018 on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society⁵, the functioning of the eHealth Digital Service Infrastructure, as well as the role of the eHealth Network within its governance should be defined.

Within the eHealth Digital Service Infrastructure, eHealth Network should drive the elaboration and coordination on the common requirements, standards and formats necessary to achieve technical, semantic and organisational interoperability between national eHealth systems. It should also develop guidelines on interoperability and exchange of electronic health records.

In order to ensure the exchange of information among Member States, the eHealth Network should assess, based on tests and audits carried out by the Commission, the technical readiness of Member States to exchange electronic health data through their National Contact Points for eHealth. The eHealth Network should work towards enabling these Member States to start exchanging patient summaries, e-prescriptions and, in the longer run, electronic health records.

In order to promote the interoperability of eHealth solutions, the eHealth Network should provide guidance on the necessary investments in the national digital infrastructure. Where appropriate, it should carry out work in other areas related to eHealth, supporting the improved delivery of healthcare through better use of health data, including with the view of advancing research and public health. It should also allow its members to exchange views on national strategic challenges with regard to new technologies and data usages.

Processing of personal data of patients, representatives of Member States, experts and observers participating in the eHealth Network, done by Member States, or other national organisations or bodies, should be carried out in accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)⁶. Processing of personal data for the purpose of managing and ensuring the security of the core services of the eHealth Digital Service Infrastructure done by the Commission should also comply with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

In accordance with the Regulation (EU) 2016/679, citizens should have the right of access and manage their personal data and to exercise that right easily and at reasonable intervals. This includes the right for citizens to have access to health data, for example the data in their medical

⁵ Communication from the Commission on enabling the digital transformation of health and care in the Digital Market; empowering citizens and building a healthier society, SWD(2018), 126 final, p.7.

⁶ OJ L 201, 31.7.2002, p. 37.

records containing data, and to safeguard portability of these data information such as diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided. To ensure compliance with Regulation (EU) 2016/679, Member States should ensure that citizens are able to exercise fully their rights regarding the access to their health data and data portability. Member States should ensure as well that their citizens are able to access and manage their own health data, and to safeguard portability of these data.

Implementing Decision (EU) 2011/890 should therefore be repealed and replaced by this Decision for reasons of legal certainty and clarity.

The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Article 16 of Directive 2011/24/EU.

Subject matter

This Decision sets the necessary rules for the management and the functioning of the eHealth Network of national responsible authorities on eHealth, as provided for by Article 14(1) of Directive 2011/24/EU.

Definitions

For the purpose of this Decision, the definitions in points 1, 2, 7, 8 of Article 4 of Regulation (EU) 2016/679 shall apply.

The following definitions shall also apply:

(a) 'Cross-Border eHealth Information Services' means services that are processed via National Contact Points for eHealth for the purpose of cross-border healthcare, following the agreement of the eHealth Network;

(b) 'eHealth Network' means the voluntary Network among Member States, pursuing the objectives indicated in Article 14 of Directive 2011/24/EU;

(c) 'National Contact Points responsible for eHealth' means national organisations identified by each participating Member State, which are acting as an organisational and technical gateway for the provision of Cross-Border eHealth Information Services;

(d) 'eHealth Digital Service Infrastructure' means Digital Service Infrastructure that enables the provision of Cross-Border eHealth Information Services via National Contact Points responsible for eHealth;

(e) 'electronic Health Record (EHR)' means comprehensive collection of medical records or similar documentations of the past and present physical and mental state of health of an individual, in digital form, which provides for ready availability of these data or medical treatment and other closely related purposes.

(f) 'core services' means central hubs of digital service infrastructures as defined in Article 2 of Regulation (EU) No 283/2014;

(g) 'shared European eHealth Services' means digital services shared between Member States, developed by the eHealth Network.

Membership of the eHealth Network

Members shall be Member States' authorities responsible for eHealth, designated by those Member States participating in the eHealth Network.

Member States wishing to participate in the eHealth Network shall notify in writing the Commission:

- a) the decision to participate in the eHealth Network;
- b) the national authority responsible for eHealth which will be part of the eHealth Network, as well as the name of the representative and of his/her alternate.

The names of national authorities may be published in the Register of Commission expert groups and other similar entities ('the Register').

Members shall notify in writing the Commission of the following:

- a) their decision to withdraw from the eHealth Network;
- b) any change in the information referred to in Article 3 (2) (b).

The Commission shall make available to the public the list of national authorities participating in the eHealth Network.

Personal data of representatives of Member States, experts and observers participating in the eHealth Network shall be processed in accordance with Regulation (EC) No 45/2001.

Tasks of the eHealth Network

In order to deliver sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare, as provided under Article 14(2)(a) of Directive 2011/24/EU, the eHealth Network may, in particular:

- a) facilitate greater interoperability of the national information and communications technology systems and transferability of cross-border electronic health data in cross-border healthcare by supporting Member States participating in the eHealth Network to establish requirements, standards and formats to achieve technical, semantic, organisational and legal interoperability between national digital healthcare systems;
- b) provide guidance to Member States on how to empower citizens to access and manage their own health data and how to safeguard the portability of these data;
- c) carry out work in other areas related to eHealth, supporting the improved delivery of healthcare through better use of health data;
- d) provide guidance to Member States participating in the eHealth Network, as well as to the Commission, on the need for investments in national digital infrastructure;

- e) develop guidelines on interoperability of electronic health records;
- f) develop, along with the Commission, the governance models of the eHealth Digital Service Infrastructure⁷ and of other shared European eHealth Services and participate in their governance. The eHealth Network may in particular:
 - i. set the priorities of the eHealth Digital Service Infrastructure or other shared European eHealth Services, and oversee their operation;
 - ii. draw up guidelines for the operation, as well as the strategy on standards used, of the eHealth Digital Service Infrastructure and for other shared European eHealth Services;
 - iii. assess whether Member States are allowed to start exchanging electronic health data through their National Contact Points for eHealth based on their compliance with the requirements, standards and formats established under (a);
 - v. approve the annual work plan and financial plan for the eHealth Digital Service Infrastructure;
 - vi. collaborate to secure funding for the eHealth Digital Service Infrastructure or other shared European eHealth Services and for their components.
 - vii. analyse and elaborate positions on cybersecurity or information security, of the eHealth Digital Service Infrastructure or other shared European eHealth Services, taking into account existing legislation and documents elaborated by EU level competent authorities. It may also share best practices in the area of national health information security and cybersecurity implementation at national level.

The eHealth Network may establish guidelines for enabling effective methods on the use of health related information for public health and research, including in relation to information deriving from eHealth Digital Service Infrastructure or other shared European eHealth Services, as assigned to it by Article 14(2)(b)(ii) of Directive 2011/24/EU.

The eHealth Network may establish guidelines, taking into account existing EU legislation, to develop common identification and authentication measures, facilitating transferability of data in cross-border healthcare, as assigned to it by Article 14(2)(c) of Directive 2011/24/EU.

Functioning of the eHealth Network

The eHealth Network shall establish its own Rules of Procedure, by simple majority of its Members on a proposal made by the Commission following consultation with the Member States participating in the Network.

The eHealth Network may decide to delegate some of the tasks referred in Article 4(f)(iii) to bodies set up in the framework of the governance model for the eHealth Digital Service Infrastructure.

The eHealth Network shall adopt a multiannual work programme and an evaluation instrument on the implementation of such programme.

⁷ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co06_en.pdf

To accomplish its tasks, the eHealth Network may set up sub-groups, including with experts to examine specific questions on the basis of terms of reference defined by the eHealth Network itself. Such sub-groups shall be disbanded as soon as their mandate is fulfilled.

In pursuing its objectives, the eHealth Network shall work in close cooperation with the Joint Actions or other supporting mechanisms and shall build on the results achieved in the framework of those activities.

Member States participating in the eHealth Network may decide to advance the cooperation in some areas covered by the tasks of the eHealth Network. Whilst the participation in cooperation is voluntary, once a Member State decided to commit to a certain form of cooperation, it is bound by its rules. The decisions on advanced cooperation shall be adopted by the Member States participating in the respective form of cooperation, in accordance with the rules of procedure of the eHealth Network.

Representatives of the Member States participating in the eHealth Network, as well as invited experts and observers, shall comply with the obligations of professional secrecy laid down by Article 339 of the Treaty of the Functioning of the European Union, as well as with the Commission's rules on security regarding the protection of EU classified information, laid down in the Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information⁸. Should they fail to respect these obligations, the Chair of the eHealth Network may take all appropriate measures.

Relation between the eHealth Network and the Commission

The Commission shall:

- (a) co-chair the meetings of the eHealth Network together with the representative of the Member States;
- (b) develop appropriate technical and organisational measures on the core services of eHealth Digital Service Infrastructure, complying with EU legislation and consistent with the use and the rules governing other digital service infrastructures;
- (c) support the eHealth Network in the exchange of the cross-border health data by providing the necessary testing to certify the technical readiness of National Contact Points for eHealth and by auditing the National Contact Points for eHealth to assess their compliance with the readiness criteria adopted by the eHealth Network, upon the request of Member States. Experts from the Member States may assist Commission experts.

The Commission may consult the eHealth Network on any matter relating to eHealth in the European Union.

Any member of the eHealth Network may advise the Commission to consult the eHealth Network on a specific question.

Secretariat of the eHealth Network

⁸ OJ L 72, 17.3.2015, p. 53

The Commission shall provide secretarial services for the eHealth Network.

Other Commission officials with an interest in the proceedings may attend meetings of the eHealth Network and its sub-groups.

The Commission shall publish relevant activities carried out by the eHealth Network either by including it in the Register or via a link from the Register to a dedicated website.

Exchanging cross-border electronic health data

Where the exchange of cross-border electronic health data takes place via the e-Health Digital Service Infrastructure, the National Contact Points for eHealth, appointed by the Member States under the eHealth Digital Service Infrastructure, shall act as a communication gateway with other Member States in delivering Cross-Border eHealth Information Services and as an interface with existing national infrastructures.

Data protection

The General Data Protection Regulation (GDPR) [and the "new" Regulation 45/2001] shall apply to the processing of personal data through the eHealth Digital Service Infrastructure set up by the European Commission.

Without prejudice to paragraph (3), the National Contact Points for eHealth shall be regarded as controllers of any processing of personal data through the eHealth Digital Service Infrastructure, in accordance with point (7) of Article 4 of the GDPR. The Commission, considering its tasks as defined in Article 7(1)(b), shall act as a processor in accordance with Article 29 of [the "new" Regulation 45/2001]. The processing of personal data by the Commission shall be governed by Annex I to this Decision.

The Commission shall be regarded as controller of processing of personal data relating to the management of access rights to the eHealth Digital Service Infrastructure, in accordance with point (8) of Article 3 of Regulation EC No 45/2001].

Expenses

Participants in the activities of the eHealth Network shall not be remunerated by the Commission for their services.

Travel and subsistence expenses incurred by participants in the activities of the eHealth Network shall be reimbursed by the Commission in accordance with the provision in force within the Commission. Those expenses shall be reimbursed within the limits of the available appropriations allocated under the annual procedure for the allocation of resources.

Repeal

Implementing Decision 2011/890 is hereby repealed. References to the repealed Decision shall be construed as references to this Decision.

Entry into force

This Decision shall enter into force on the day following that of its publication in the Official Journal of the European Union.

Addressees

The Decision is addressed to the Member States.

General Obligations related to Data Protection

For the purpose of supporting Member States in providing cross-border eHealth services to exchange patients and health care professionals' data, the Commission shall manage and ensure the security of the core services of the eHealth Digital Service Infrastructure throughout the period in which such exchange takes place.

Patients and health care professionals' data shall include personal data necessary for their identification and authentication as well as data relating to patients' health data such as diagnoses, examination results, and assessments reports by treating healthcare professional and any treatment or surgery provided.

The Commission shall not access patients' personal data exchanged through the eHealth Digital Service Infrastructure, unless this is necessary to comply to specific documented instructions from the controller, in particular in accordance with paragraph 3 (a), (d), (f) and (g) of this Annex.

The Commission shall:

- (a) process the personal data only on documented instructions from the controller, including with regard to transfers of personal data to a third country or an international organisation, unless required to do so by law to which the processor is subject; in such a case, the processor shall inform the controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
- (b) ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
- (c) take all measures required pursuant to Article 33 (Security of processing) of [the "new" Regulation 45/2001];
- (d) taking into account the nature of the processing, assist the controller by appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the controller's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III of the GDPR;
- (e) assists the controller in ensuring compliance with the obligations pursuant to Articles 32 to 36 of the GDPR taking into account the nature of processing and the information available to the processor;

(f) at the choice of the controller, delete or return all the personal data to the controller after the end of the provision of services relating to processing, and delete existing copies unless Union or Member State law requires storage of the personal data;

(g) make available to the controller all information necessary to demonstrate compliance with the obligations laid down in this Annex and allow for and contribute to audits, including inspections, conducted by the controller or another auditor mandated by the controller. The processor shall immediately inform the controller if, in its opinion, an instruction infringes this Regulation or other Union or Member State data protection provisions.

The Commission shall not engage another processor without prior specific or general written authorisation of the controller. In the case of general written authorisation, the Commission shall inform the controller of any intended changes concerning the addition or replacement of other processors, thereby giving the controller the opportunity to object to such changes.

Where the Commission engages another processor for carrying out specific processing activities on behalf of the controller, the same data protection obligations as set out in this Annex shall be imposed on that other processor, in particular providing sufficient guarantees to implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of applicable legislation. Where that other processor fails to fulfil its data protection obligations, the Commission shall remain fully liable to the controller for the performance of that other processor's obligations.