



Brussels, 6.2.2019
C(2019) 800 final

COMMISSION RECOMMENDATION

of 6.2.2019

on a European Electronic Health Record exchange format

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Citizens have the right to access their personal data, including their health data as provided for by Regulation (EU) 2016/679 of the European Parliament and of the Council¹, which lays down the conditions for lawful processing of personal data, including data concerning health, as defined therein² (health data). However most citizens cannot yet access (nor securely share) their health data across borders.
- (2) The ability of citizens and healthcare providers to securely access and share electronic health records ('EHR's), that is to say collections of longitudinal medical records or similar documentation of an individual, in digital form, within and across borders has a number of benefits: an improvement in the quality of care for citizens, reduction in the cost of health care to households, and it supports the modernisation of health systems in the Union that are under pressure from demographic changes, rising expectations and costs of treatment. For example, sharing the results of blood tests in a digital format among clinical teams prevents repeating invasive and costly tests on the same person. Similarly, where patients need to see different health professionals, sharing electronic health records can avoid a repetition of the same information about their medical history saving time for all parties involved and improving the quality of care.
- (3) Enabling the secure access and sharing of health records across borders in the Union will facilitate citizens' life in a number of cross-border situations, such as citizens, and their families, who are currently living in another Member State for work purposes or retired people living in another country, enabling them to have access to health records between the Member States in which they have been resident. It will also improve the quality of care in situations which require medical treatment while travelling in the Union or as part of a cross border agreement. There are over two million recorded instances a year where a citizen living in one Member State has sought health care in

¹ 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, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

² Article 4(15) of the General Data Protection Regulation.

another³. Moreover, in the future, it can be usefully linked to European Union initiatives in the field of social security coordination.

- (4) Health care needs are expected to further increase in the future as a result of population ageing, rising prevalence of chronic conditions and a rise in demand for long-term care. This is evidenced by health spending amounting to 9.6% of Gross Domestic Product in the Union as a whole in 2017, up from 8.8% in 2008⁴. Similarly, evidence from various countries suggest that up to 20% of health care spending is wasteful, for example because patients receive unnecessary tests or treatments, or as a result of avoidable hospital admissions.
- (5) Digital technologies are powerful solutions to address those issues and to adapt health systems to future challenges. For example, digital solutions linked to health apps, or wearable devices, combined with a system that allows a citizen secure access to their own health data, should enable patients with chronic conditions, such as diabetes, or cancer, to monitor their own symptoms at home and share them quickly with their clinical teams. This should reduce the number of visits to a health facility for monitoring. Digital technologies can also help to detect early a need for a change in treatments, resulting in fewer hospitalisations due to complications. Better management of chronic conditions in the community, alongside reducing duplication of health care actions (such as tests) should not only make systems more sustainable but also improve overall quality of life, the quality of health care provided to citizens, and reduce the costs associated with health care for individuals and households.
- (6) The Council has regularly called for Member States to strengthen the implementation of their digital health strategies. In particular, the Council conclusions on Health in the Digital Society adopted on 8 December 2017⁵ stress the need for Member States to make their electronic health systems more interoperable in order to give citizens greater control over their health data.
- (7) To support the digital transformation of health and care, the Commission adopted the Communication on ‘enabling the digital transformation of health and care in the Digital Single Market: empowering citizens and building a healthier society’⁶. That Communication adapts for the health sector, the objectives set out in the Communication ‘A Digital Single Market Strategy for Europe’ adopted on 6 May 2015⁷ and the Communication ‘EU eGovernment Action Plan - Accelerating the Digital Transformation of Government’, adopted on 19 April 2016⁸. It addresses the concerns raised in the Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy, ‘A Connected Digital Single Market for All’⁹ regarding the fact that the uptake of digital solutions for health and care remains slow and varies significantly across the Member States and regions.
- (8) Digitising health records, and creating systems that enable them to be securely accessed by citizens and securely shared within and between the different actors in the

³ Either using a European Health Insurance Card or under the 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 healthcare (OJ L 88, 4.4.2011, p. 45).

⁴ ‘Health at a Glance: Europe 2018 - State of Health in the EU Cycle’
https://ec.europa.eu/health/sites/health/files/state/docs/2018_healthatglance_rep_en.pdf

⁵ 2017/C 440/05.

⁶ COM(2018) 233 final.

⁷ COM(2015) 192 final.

⁸ COM(2016) 179 final.

⁹ COM(2017) 228 final.

health system (patients, their clinical teams in the community and hospital facilities) is an important step towards integrating digital technologies into health and care approaches. That integration requires electronic health records, to be interoperable across the Union whereas currently many of the formats and standards in electronic health record systems – that are information systems for recording, retrieving and managing electronic health records – used across the Union are incompatible.

- (9) New technologies for health should support citizens to become active agents of their own health journey. To this end, citizens' and patients' needs should be taken into account when designing health information systems including making these systems more accessible to users, in particular to persons with disabilities, according to the accessibility requirements laid down by Directive (EU) 2016/2102 of the European Parliament and of the Council¹⁰, where applicable
- (10) The aim of interoperability with regard to electronic health records is to allow for the processing of information in a consistent manner between those health information systems, regardless of their technology, application or platform in a way that it can be meaningfully interpreted by the recipient.
- (11) The lack of interoperability with regard to electronic health records leads to fragmentation and a lower quality of cross-border healthcare provision. The Commission has already identified specific 'Integrating the Healthcare Enterprise' (IHE) profiles listed in the Annex to Commission Decision (EU) 2015/1302^{11,12} with the potential to increase interoperability of eHealth services and applications to the benefit of citizens and the healthcare professional community and to be eligible for referencing in public procurement. Those profiles provide detailed specifications for different layers of interoperability. Some of those profiles are already used to address specific business requirements in the eHealth Digital Service Infrastructure ('eHDSI').
- (12) The highest possible standards for security and data protection are central to developing and exchanging electronic health records. The General Data Protection Regulation requires patient data to be protected and properly secured so that its confidentiality, integrity and availability are ensured. As a consequence, systems must be secure, safe, trustable and integrate data protection by design and by default. A series of European wide digital solutions and common approaches for government and institutions lay the basis for this.
- (13) The use of secure electronic identification and authentication means provided for in Regulation (EU) No 910/2014 of the European Parliament and of the Council¹³ (eIDAS) should enhance access, security and trust in electronic health record systems. That Regulation lays down the conditions under which recognised electronic identification means, falling under a notified electronic identification scheme of a Member State, may be used by citizens to gain access to online public services from abroad, including access to health services and health data. It also lays down rules for trust services such as electronic signatures, electronic seals and electronic registered

¹⁰ Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (Web Accessibility Directive) (OJ L 327, 2.12.2016, p.1-15).

¹¹ Commission Decision (EU) 2015/1302 of 28 July 2015 on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement (OJ L 199, 29.7.2015, p. 43).

¹² <https://www.ihe.net/> and <https://www.ihe-europe.net/>

¹³ Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

delivery services, to securely manage and exchange health data by minimising the risk of possible tampering and misuse.

- (14) Under Directive (EU) 2016/1148 of the European Parliament and of the Council¹⁴ healthcare providers, that are identified as operators of essential services by Member States and digital service providers falling in its scope are required to take appropriate and proportionate technical and organisational measures to manage the risks posed to the security of network and information systems they use in their operations of provision of service. They are also required to notify security incidents having a significant or substantial impact on the continuity of the services they provide to the competent national authorities or to the national Computer Security Incident Response Teams (CSIRTs). As regards in particular cybersecurity for electronic health record systems, cybersecurity certification may allow the demonstration that cybersecurity requirements are fulfilled, under the relevant Union cybersecurity framework¹⁵.
- (15) Member States have taken important steps to foster interoperability with the support of the Commission, through the activities of the eHealth Network established under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council. The eHealth Network's main objective is to support the development of sustainable eHealth systems, services and interoperable applications, facilitate cooperation and the exchange of information among Member States, enhance continuity of care and ensure access to safe and high-quality healthcare. Consequently it plays a crucial role for the interoperability of electronic health records.
- (16) In particular, in order to facilitate the interoperability of European eHealth systems, a number of Member States participating in the eHealth Network have worked together with the Commission to build the eHealth Digital Services Infrastructure, supported by the Connecting Europe Facility (CEF) Programme¹⁶. In some of those Member States, the exchange of 'ePrescriptions' between health professionals across borders through the eHealth Digital Services Infrastructure has started, while the exchange of 'Patient Summaries' is expected to start soon. Enhancing the interoperability of electronic health records should help expanding the datasets currently being exchanged within the eHealth Digital Services Infrastructure to include valuable information concerning laboratory results, medical imaging and reports, and hospital discharge reports, which would enhance continuity of care. A number of tools developed for the eHealth Digital Services Infrastructure are a resource for Member States for the exchange of electronic health records.
- (17) In the context of exchanging electronic health records, the eHealth Network plays a valuable role in further developing the European electronic health record exchange format, by using it for the eHealth Digital Services Infrastructure and promoting its use for exchanges between healthcare providers at national level.
- (18) Digitising health records and enabling their exchange could also support the creation of large health data structures which combined with the use of new technologies, such as big data analytics and artificial intelligence can support the search for new scientific discoveries.

¹⁴ Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).

¹⁵ See Joint Communication on Resilience, Deterrence and Defence: Building strong cybersecurity for the EU, point 2.2 (JOIN(2017) 450 final).

¹⁶ <https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHealth+DSI+Operations+Home>

- (19) Existing national specifications for electronic health record systems may continue to apply in parallel with a European electronic health record exchange format,

HAS ADOPTED THIS RECOMMENDATION:

OBJECTIVES

- (1) This Recommendation sets out a framework for the development of a European electronic health record exchange format in order to achieve secure, interoperable, cross-border access to, and exchange of, electronic health data in the Union.

The framework includes:

- (a) a set of principles that should govern access to and exchange of electronic health records across borders in the Union;
- (b) a set of common technical specifications for the cross-border exchange of data in certain health information domains, which should constitute the baseline for a European electronic health record exchange format;
- (c) a process to take forward the further elaboration of a European electronic health record exchange format.

It also encourages Member States to ensure secure access to electronic health record systems at national level.

ELECTRONIC HEALTH RECORD SYSTEMS IN MEMBER STATES

Ensuring secure access to electronic health record systems

- (2) Member States should ensure that electronic health record systems meet high standards for the protection of health data, and the security of network and information systems on which such electronic health record systems rely, to avoid data breaches and minimise the risks of security incidents.
- (3) Member States should ensure that citizens and their healthcare professionals have online access to their electronic health records using secure electronic identification means, taking into account the framework for security and trust established by the Regulation (EU) No 910/2014.

Tools and incentives

- (4) Member States should use the tools and building blocks provided by the eHealth Digital Services Infrastructure supported under the Connecting Europe Facility Programme and refer to the Refined eHealth European Interoperability Framework¹⁷ as the common framework for managing interoperability in the eHealth domain.

¹⁷

https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

- (5) Member States should take appropriate measures to support the use of interoperable electronic health record systems such as leveraging dedicated financial investments, including incentive mechanisms, and adapting legislation where appropriate.

National digital health networks

- (6) To enhance the interoperability and security of national health systems and support the secure exchange of health data across borders, each Member State should set up a national digital health network involving representatives of the relevant competent national authorities and, where appropriate, regional authorities dealing with digital health matters and the interoperability of electronic health records, and security of networks and information systems, and the protection of personal data. In particular national digital health networks should involve the following:
- (a) the national representative of the eHealth Network;
 - (b) national, or regional, authorities with clinical and technical competence for digital health matters;
 - (c) supervisory authorities established under Article 51 of Regulation (EU) 2016/679;
 - (d) competent authorities designated pursuant to Directive (EU) 2016/1148.
- (7) The results of discussions or consultations of the national digital health networks should be transmitted to the eHealth Network and to the Commission.

FRAMEWORK FOR CROSS-BORDER EXCHANGE OF ELECTRONIC HEALTH RECORDS

Principles for access to and cross-border exchange of electronic health records

- (8) Member States should ensure that citizens are able to access and securely share their electronic health data across borders.
- (9) Member States are encouraged to give citizens the ability to choose to whom they provide access to their electronic health data, and which health information details are shared.
- (10) Member States should ensure that the principles set out in the Annex are observed when developing solutions enabling access to, and exchange of electronic health data in the Union.

Baseline for a European electronic health record exchange format

- (11) Member States should take measures to ensure that the following health information domains, as a baseline, are part of a European electronic health record exchange format:
- (a) Patient Summary;
 - (b) ePrescription/eDispensation;
 - (c) Laboratory results;
 - (d) Medical imaging and reports;

- (e) Hospital discharge reports.

The cross-border exchange of information should take place in accordance with the baseline standards, interoperability specifications and the profiles depending on the health information domain as set out the Annex.

Further elaboration of a European electronic health record exchange format

- (12) Member States should, in the context of Article 14 of Directive 2011/24/EU and in collaboration with the Commission, support the further elaboration of the recommended baseline of health information domains and specifications for a European electronic health record exchange format, through a joint coordination process.
- (13) Through this process, Member States, supported by the Commission, should engage in discussions and cooperation at Union level with relevant stakeholders, including healthcare professional organisations, national competence centres, industry actors and patient groups, as well as other Union and national authorities with competence in relevant areas to encourage, and contribute to, an iterative process of further elaborating and adopting a European electronic health record exchange format. In particular, clinical and technical experts should be involved in work concerning technical and semantic specifications for cross-border exchange of health data. The results of these discussions and consultations should be transmitted to the eHealth Network.
- (14) The joint coordination process should benefit from knowledge available in national competence centres targeting the identification of the meaningful medical concepts for each given context.
- (15) The joint coordination process should take forward approaches that all Member States can support, while Member States that so wish may progress towards electronic health record interoperability at a faster speed.
- (16) The joint coordination process should build on, and incorporate the results of, existing initiatives of the eHealth Network such as the Common Semantic Strategy task force.
- (17) Member States, in the context of the eHealth Network, should cooperate with the Commission and other relevant stakeholders in establishing practical implementation guidelines, sharing good practice and promoting awareness actions for citizens and healthcare providers on the benefits of access to, and exchange of electronic health record, across borders. Pilot projects including research, innovation or deployment actions, such as those supported under the Horizon 2020¹⁸ and Connecting Europe Facility Programmes, where relevant, should be used to advance interoperability and raise awareness.

¹⁸ <https://ec.europa.eu/programmes/horizon2020/en/>

MONITORING AND FUTURE DEVELOPMENTS

Monitor progress towards interoperability

- (18) Member States, in the context of the eHealth Network and in cooperation with the Commission, should monitor progress towards interoperability on the basis of a shared roadmap revised annually, identifying common priorities, tasks, deliverables and milestones.

For that purpose, Member States should, on a yearly basis:

- (a) share information on the measures they have taken to support the adoption of the specifications of the European electronic health record exchange format;
 - (b) identify common priorities and synergies with national strategies to improve cross-border exchange of electronic health records.
- (19) The elements referred to in points 18 (a) and (b) should be taken into account when assessing the next steps for the exchange of electronic health records across the Union.

Future work

- (20) Member States should engage with the Commission and relevant stakeholders to identify and review emerging technological and methodological innovation and identify appropriate steps to achieve progress in the long-term exchange of electronic health records.

Assessment of the effects of the Recommendation

- (21) Member States should cooperate with the Commission to assess the effects of this Recommendation taking into account their experience and any relevant technological developments with a view to determine appropriate ways forward.

Done at Brussels, 6.2.2019

For the Commission
Mariya Gabriel
Member of the Commission

