EU Recommendation

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

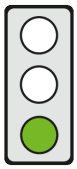
cep**PolicyBrief** No. 15/2019

Centrum für Europäische Politik

KEY ISSUES

Objective of the Recommendation: The Commission wants to facilitate cross-border healthcare in the EU by means of a voluntary European exchange format for electronic health records.

Affected parties: All citizens in their capacity as patients; healthcare providers, particularly doctors, and health insurance companies.



Pro: (1) By providing data in the language of the relevant country, the European exchange format strengthens the fundamental freedoms of EU citizens in the area of cross-border healthcare.

(2) It may also indirectly support the introduction of interoperable electronic health records at national level.

(3) The European exchange format does not restrict the Member States' protected freedom of discretion regarding the organisation of the healthcare sector.

Contra: -

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Recommendation (EU) 2019/243 of the Commission of 6 February 2019 **on a European Electronic Health Record exchange format**

Brief Summary

- **Objective of the Recommendation**
  - Electronic health records (EHRs) are collections of personal medical records or similar documents in digital form [see Recital 2].
  - EU citizens have the right to cross-border access to their personal health data in accordance with the General Data Protection Regulation (GDPR) [Recital 1].
  - In order to facilitate cross-border access to and exchange of health data, the Commission wants to promote the interoperability of electronic health records (EHRs) [see also Recitals 2, 3 and 10].
  - The Recommendation aims to support the technical development and further elaboration of a European format for the cross-border exchange of electronic health data [No. 1].
  - A Recommendation is not legally binding [Art. 288 (5) TFEU].

- **Background**
  - There are more than two million recorded instances a year of citizens seeking healthcare in a Member State other than their home state [Recital 3].
  - The Patient Mobility Directive [2011/24/EU; see cep**PolicyBrief**] on the application of patients' rights in cross-border healthcare contains rules
    - on access to cross-border healthcare and
    - on the reimbursement of costs.
    This gives rise to a general right for EU citizens to receive medical treatment in another EU country and to have the costs reimbursed via national reimbursement systems insofar as they would be covered with regard to a similar treatment in the home country.
  - In 2011, the "eHealth Network" was created on the basis of the Patient Mobility Directive in order to facilitate the coordination between the Member States in the area of electronic healthcare services. This body is made up of the authorities that are responsible for "eHealth" in the Member States. Both participation in and cooperation via the "eHealth Network" are currently voluntary. Cooperation takes place inter alia in working groups such as the "eHealth Member States Expert Group" (eHMSEG).
  - The cross-border exchange of data takes place via a technical infrastructure set up by the Member States and the EU called "eHealth Digital Service Infrastructure" (eHDSI) [Recital 16].

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– Due to the voluntary nature of cooperation via the "eHealth Network", Member States wishing to take part in cross-border healthcare services must inter alia sign an agreement drafted by the "eHealth Network" ("eHealth Agreement").

► **Electronic health record systems in the Member States**

– National EHRs are based on electronic health record systems, i.e. information systems for recording, retrieving and managing health records. Existing electronic health record systems in the EU – even within individual Member States – are often incompatible due to varying formats and technical standards. [see Recital 8]
– Member States should ensure that the electronic health record systems meet high standards of data-protection and technical security in order to avoid inter alia data breaches [No. 2].
– The existing national specifications for electronic health record systems can still be used in parallel to the European exchange format for EHRs [Recital 19].

► **Access to and cross-border exchange of health data**

– Member States should ensure that
  - their citizens and their healthcare providers have online access to their EHRs [No. 3] and
  - citizens can decide with whom and to what extent they are going to share their health data [No. 9].
– In developing solutions for accessing and sharing electronic health data, eight principles should be observed (P 1-8) [No. 10 in conjunction with No. 1 a) - h) of the Annex to the Recommendation]:
  - P 1: Citizen-centric design of the access to electronic health data [a)], particularly by observing the principle of "data protection by design" and by default [see Art. 25 GDPR].
  - P 2: Comprehensiveness and machine-readability of health data in EHRs in order to support healthcare providers and allow re-use of the data [b)].
  - P 3: Confidentiality of health data and cross-border access thereto [c)].
  - P 4: Ensuring that the processing of health data complies with data protection rules and is always based on the explicit consent of the citizen [d)].
  - P 5: Registration and verification of any processing of health data for the purpose of auditing the access to and exchange of electronic data records [e)].
  - P 6: Technical and organisational security of electronic health record systems, particularly by measures which also involve protection against unauthorised or unlawful processing, and against accidental loss, damage or destruction [f)].
  - P 7: Reliable identification and authentication of citizens, among others, in order to allow them secure access to online services that are provided in another Member State [g)].
  - P 8: Continuity and availability of EHRs in order to guarantee continuity of care [h)].

► **Baseline for a European EHR exchange format**

– Five information categories (IC 1-5) are of particular clinical relevance for cross-border healthcare. The Commission therefore gives them a high priority. They will form the baseline for a European EHR exchange format [No. 11 (1) in conjunction with No. 2.1 of the Annex to the Recommendation]:
  - IC 1: Patient Summaries, containing inter alia information about allergies, vaccinations and medicines,
  - IC 2: ePrescriptions and eDispensations of medicines,
  - IC 3: Laboratory results,
  - IC 4: Medical imaging and reports,
  - IC 5: Hospital discharge reports.
– The Recommendation contains specifications and standards for structuring the content of EHRs. It refers to existing guidelines adopted by the "eHealth Network" for the cross-border exchange of Patient Summaries and ePrescriptions and eDispensations of medicines [No. 2.2.1 of the Annex to the Recommendation]. Following signature of the eHealth Agreement, these guidelines must be complied with by the relevant Member State.
– The relevant information will be translated into the language of the country of destination (see eHMSEG, Semantic Assets rationale for Maintenance and Evolution under the eHDSI time frame, V1.0, p. 18).
– In the context of the "eHealth Network" and in collaboration with the Commission, Member States should further develop and expand the European exchange format [No. 12 in conjunction with No. 2 (2) of the Annex to the Recommendation].

Policy Context

In the second eHealth Action Plan 2012-2020, the Commission already identified obstacles to the expansion of eHealth services in 2012 and drafted targets, particularly for improved interoperability (see COM(2012) 736, p. 6-13). In the Communication on enabling the digital transformation of health and care in the Digital Single Market, the Commission emphasised that the exchange of health data as part of the digitisation of the health sector is also crucial for cross-border healthcare (see COM(2018) 233, p. 1 and 5-8).

Options for Influencing the Political Process

Directorates General:	DG Communications Networks, Content and Technology (leading); DG Health and Food Safety
Federal Ministries:	Federal Ministry of Health (leading)
Committees of the German Bundestag:	Health (leading)

ASSESSMENT

Economic Impact Assessment

EU citizens should be able to move freely within the EU internal market and avail themselves of services without any internal borders. **By providing data** and making it available **in the language of the relevant country, the EHR exchange format strengthens the fundamental freedoms of EU citizens in the area of cross-border healthcare.** The health data exchanged via eHDSI infrastructure facilitates a prospectively higher quality of care in other EU countries and promotes the use of cross-border healthcare services.

Health records that are available across borders also increase competition between European healthcare providers. This may lead, at least in part, to a shift in the demand for and supply of healthcare services between the Member States.

The Recommendation respects a person's right to their own data as patients will be able to decide for themselves, which health data they are going to share with whom. This may however result in important data being withheld which could lead to incorrect treatments and thus consequential damage to health and higher costs. The extent to which a patient's freedom of choice is appropriate with respect to the sharing of health data under the premise of a solidarity-based healthcare system is a fundamental question that cannot be addressed here.

The use of the exchange format does require technical measures and investments to be made at national level which also give rise to increased complexity for the national healthcare systems, ministries and authorities involved. However, a functioning technical infrastructure for the cross-border exchange of health data already exists at EU level, viz. the eHDSI infrastructure, so that no additional funds need to be deployed in this regard.

By requiring uniform specifications and standards, **the Recommendation may also indirectly support the introduction of interoperable EHRs at national level. These may, for their part,** due to the improved availability of data, **improve quality of care** and reduce both unnecessary duplication of examinations and incorrect prescriptions, which may lead to cost savings.

National investment in technical measures to provide for compatibility with the European exchange format may also reduce the technical fragmentation of electronic health record systems within a Member State. As a result, the investment will give rise to more efficient working processes and higher quality of care. Convergence of the electronic health record systems will thus bring about long-term socio-economic benefits: With more readily available data, the patient can be treated more quickly and effectively. In addition, increased efficiency means that resources can be used for other activities, such as allowing doctors more time to talk to their patients.

In the interests of an effective use of resources, **Member States should integrate the** Commission's **proposed specifications and standards for the European exchange format into their national EHRs** right from the start. Where data is exchanged without using the same standards, there is a risk of data being lost. This may be detrimental to the healthcare of the affected citizen. **Developing interoperability at a later date is technically more complex and involves a correspondingly higher level of costs.**

The uniform specifications and standards for EHRs, recommended by the Commission, may also facilitate continuous monitoring of safety and effectiveness and thereby of the benefit of medicines ("real world evidence") both nationally and EU-wide. This is especially relevant for medicines that are approved in accelerated procedures ("early access schemes"). The structures required for monitoring do not yet exist throughout the EU. Until now, data on medicines used in routine care is mainly available via the billing data from health insurance companies. Yet, these do not contain information on treatment outcomes. Such information is, however, essential for evaluating the benefit of medicines following approval in routine care. The results thereby recorded would enable an adjustment of decisions made on the reimbursement of such medicines and recommendations for standard therapies.

In carrying out the planned **further development of the exchange format, attention must be given to ensuring a high level of suitability for everyday use** and user-friendliness. **In this regard, the professional** experience and **requirements of service providers**, particularly doctors, **must be taken into account** because only then will the

exchange format actually be used thereby reducing costs for service providers and ensuring a return on the investment in the long term.

Legal Assessment

Legislative Competency

Unproblematic because the Commission has made use of its general competence to adopt recommendations [Art. 292 TFEU]

Subsidiarity

Unproblematic because the exchange format for EU-wide cross-border access to and exchange of health data can be developed better at EU level.

Proportionality with Respect to Member States

Unproblematic, including as regards **the requirements relating to national health record systems**: They **are so generally worded that they do not restrict the Member States' protected freedom of discretion** [Art. 168 (7) TFEU] In particular, Member States can apply national specifications in parallel to the European exchange format.

Compatibility with EU Law in other respects

Unproblematic.

Impact on German Law

There is no direct impact because the Recommendation is non-binding. Nevertheless, recommendations aim to influence the development process in the Member States. In the context of work on the technical and infrastructural development of EHRs, the Recommendation should be adhered to when setting up national health record systems.

Conclusion

By providing data in the language of the relevant country, the European exchange format strengthens the fundamental freedoms of EU citizens in the area of cross-border healthcare. The Recommendation may also indirectly support the introduction of interoperable EHRs at national level. These may, for their part, improve quality of care. Member States should integrate the proposed specifications and standards for the European exchange format into their national EHRs. Developing interoperability at a later date is technically more complex and involves a correspondingly higher level of costs. In carrying out further development of the exchange format, attention must be given to ensuring a high level of suitability for everyday use. In this regard, the professional requirements of service providers must be taken into account. The requirements relating to national health record systems are so generally worded that they do not restrict the Member States' protected freedom of discretion.