

Amendment 544
Eugen Jurzyca, Beata Kempa
 on behalf of the ECR Group

Report
Tomislav Sokol
 European Health Data Space
 (COM(2022)0197 – C9-0167/2022 – 2022/0140(COD))

A9-0395/2023

Proposal for a regulation
Article 70 – paragraph 1

Text proposed by the Commission

1. After 5 years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of **the** self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies.

Amendment

1. After 5 years from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of:

(a) the effectiveness of self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by notified bodies ***or any other measure to facilitate market surveillance of EHR systems and ensure the functioning of the market; Member States shall provide the data and information necessary to conduct a thorough assessment;***

(b) the impacts of EHR systems on health outcomes for patients;

(c) the impacts of EHR systems on healthcare economic performance;

(d) the security, resilience and flexibility of the EHR systems and secondary data sharing framework, in order to assess the

readiness for potential future crises;

(e) the interoperability model in place in Member States, including best practices analysis;

(f) the quality and coverage of access of health professionals to the medical records of patients per Member State, including the impact on reduction of duplications and errors and reduction of administrative time and costs;

(g) overlaps and incoherences with other Union and national legislation, including the quantification of related extra costs of overlaps and related regulatory uncertainty. Inter alia, the assessment shall analyse alignment with the General Data Protection Regulation, Data Governance Act, Data Act, AI Act and the Regulations on cybersecurity.

Or. en

Justification

The purpose of this amendment, adopted in IMCO as Amendment 114, is to measure results delivered to consumers and patients. These results may include reduced healthcare costs, faster diagnosis and treatment times, and overall improvement in health outcomes.

6.12.2023

A9-0395/545

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Proposal for a regulation

Article 70 – paragraph 2

Text proposed by the Commission

2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.

Amendment

2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. ***The overall evaluation shall also identify best practices and assess the health outcomes for patients and consumers resulting from implementation of the EHDS.***

Or. en

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Proposal for a regulation
Article 70 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The Commission shall be empowered to adopt, by ... [12 months after the date of entry into force of this Regulation], delegated acts to supplement this Regulation in order to:

(a) set out the common result and impact-oriented indicators to be used for reporting on the progress and for the purpose of monitoring and evaluation of this Regulation;

(b) measure the costs, benefits and other health and economic results, including trends per Member State, in order to compare the effectiveness of implementation of this Regulation; and

(c) define a methodology for reporting by Member States.

The Commission shall regularly revise and, if necessary, update the common indicators.

Or. en

Justification

The purpose of this amendment, adopted in IMCO as Amendment 117, is to measure results delivered to consumers and patients. These results may include reduced healthcare costs, faster diagnosis and treatment times, and overall improvement in health outcomes. The inclusion of indicators facilitates the comparison of implementation among Member States and the identification of best practices.

