This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission departments and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down data quality requirements for the registration of personal electronic health data

pursuant to Article 13(4) of Regulation (EU) 2025/327.

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847,[1] and in particular Article 13, paragraph (4), thereof,

Whereas:

(1) Regulation (EU) 2025/327 on the European Health Data Space ('EHDS') seeks to improve natural persons' access to and control over their personal electronic health data in the context of healthcare and to improve the cross-border exchange of such data to ensure continuity of healthcare. To this end, the Commission is tasked pursuant to Article 13(4) to determine data quality requirements for the registration of personal electronic health data in an electronic health record ('EHR') system. Establishing common registration requirements of personal electronic health data across Member States is fundamental to deliver high-quality data necessary for safe cross-border healthcare provision.

(2) To ensure a realistic and workable solution across Member States and noting existing divergent registration methods, this Regulation introduces registration requirements with a clearly defined scope, focusing on the registration of data in a structured form. This approach intends to ensure EU-wide interoperability and a sufficient degree of uniformity, while taking due account of the respective national contexts and avoiding disproportionate burden on healthcare providers. To this end, the requirements ensuring

[1] OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

data quality in registration that are established in this Regulation are consistent with the European electronic health record exchange format ('EEHRxF'), as laid down in Commission Implementing Regulation [Reference to implementing act adopted pursuant to Article 15 of Regulation (EU) 2025/327].

(3) In order to enhance the uniformity and interoperability of registered personal electronic health data, these common registration requirements should focus on health data that are essential to ensure the safe and effective identification, assessment and treatment of a patient through their availability in a structured form easily comprehensible by health professionals, in particular in situations where timely access to such data is needed. For the purposes of this Regulation, essential health data should be understood as a subset of personal electronic health data that belong to the priority categories, that comprise, at a minimum, core patient identification and demographic data necessary to reliably establish the identity of the patient; alerts containing information on matters requiring the immediate attention of health professionals; information on allergies and intolerances; information on known conditions; relevant information on procedures previously performed; and information on implantable or other medical devices present in the patient's body.

(4) Where essential health data are registered in an EHR system by healthcare providers, and as applicable to the specific healthcare condition of a natural person, such registration should be performed in accordance with the requirements set out in Annex I. While the decision to perform or not a registration of essential health data rests with healthcare providers, any such registration should be carried out in a structured format, so that those data can be efficiently exchanged, readily retrieved and effectively re-used for the provision of healthcare across different healthcare settings. Such structured registration should contribute to making those data more uniform, consistent and reusable, thereby supporting continuity of care, patient safety and quality of healthcare.

(5) The essential health data referred to in this Regulation should be identified using the elements set out in Commission Implementing Regulation [Reference to implementing act adopted pursuant to Article 15 of Regulation (EU) 2025/327]. That Regulation defines a common baseline of semantic and technical capabilities, facilitating interoperability in the exchange of personal electronic health data belonging to the priority categories, as defined in Regulation (EU) 2025/327. By contrast, this Regulation lays down the minimum quality requirements where a healthcare provider registers such data, so that registration is performed in a structured form. This ensures their availability for future exchanges in accordance with the objectives of Regulation (EU) 2025/327.

(6) If essential health data evolves over time, the healthcare provider must update the existing record with those changes, so that it remains a single and updated version. Where an existing record cannot be updated, a new instance should be created instead and the previous instance should be clearly marked as obsolete. Within a single healthcare provider there should not be multiple active instances of the same data, except where this cannot be avoided due to technical or operational reasons. Where multiple active instances exist, consistency between them should be ensured.

(7) In order to ensure that data registered and maintained throughout the registration process are accurate, complete, consistent, interoperable and up to date, the data quality requirements laid down in this Regulation should apply to the registration process managed by healthcare providers as a whole. Moreover, healthcare providers ought to implement organisational, technical and procedural measures supporting structured data generation, including automated quality checks, where appropriate.

(8) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) of the European Parliament and of the Council 2018/1725[2] and delivered an opinion on xxxxx.

(9) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 98(1) of Regulation (EU) 2025/327.

HAS ADOPTED THIS REGULATION:

Chapter 1
GENERAL PROVISIONS

Article 1

Subject matter

1. This Regulation establishes data quality requirements for the registration of priority categories of personal electronic health data referred to in Article 14(1) of Regulation (EU) 2025/327 in electronic health record (EHR) systems.

Article 2

Definitions

For the purposes of this Regulation the following definitions apply:

(1) 'essential health data' means the set of data listed in Annex I.

Article 3

Data quality requirements for the registration of personal electronic health data

1. Where information belonging to the essential health data is registered in an EHR system pursuant to Article 13 paragraph 1 of Regulation (EU) 2025/327, registration shall be done in a structured form in accordance with the requirements set out in Annex I.
2. Healthcare providers may register the essential health data in an EHR system in accordance with paragraph 1 through the:
   (a) manual entry of data;
   (b) automatic generation or entry of data; or
   (c) import of data from another data source.
3. When registering information belonging to the essential health data pursuant to paragraph 1, healthcare providers shall avoid registering the same data in multiple EHR systems or through multiple records within one system. Where registration in multiple

[2] Regulation (EU) 2018/1725 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data (OJ L 295, 21.11.2018, pp. 39–98, ELI: http://data.europa.eu/eli/reg/2018/1725/oj)

systems is necessary due to technical or operational reasons, healthcare providers shall ensure consistency between the data registered in different systems.

Where updated information belonging to the essential health data is available, healthcare providers shall update the relevant records accordingly.

4. Where [implementing act under Article 15 EHDS] requires the use of the data type 'CodeableConcept' for fields relating to an essential health data element, that element shall be registered using a coding system designated for that element in [implementing act under Article 15 EHDS] or a national coding system for which the Member State has provided mapping rules in accordance with Article 7(2) of [implementing act under Article 15 EHDS].

Article 4

Entry into force and application

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

This Regulation shall apply from 26 March 2029.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President

ANNEX I

***Table 1* - Requirements for the registration of essential health data in a structured form.**

Essential health data element name(s) as set out in Annex XI of [IA 15]	**Additional rules**	**Date from which registration in a structured form shall be performed in accordance with the requirements set out in Annex XI of [IA 15]**
EHDSPatient.identifier.type, EHDSPatient.identifier.value, EHDSPatient.identifier.system EHDSPatient.name EHDSPatient.dateOfBirth EHDSPatient.administrativeGender	Registration of identifiers shall be performed in accordance with the set of healthcare attributes issued pursuant to Article 3(2) of Commission Implementing Regulation (EU) 2026/2099.	26 March 2029
EHDSPatient.sexForClinicalUse		26 March 2031
EHDSPatient.deceased[x]		26 March 2033
EHDSAlert.code EHDSAlert.period		26 March 2031
EHDSAlert.priority		26 March 2033
EHDSAllergyIntolerance.agentOrAllergen EHDSAllergyIntolerance.criticality		26 March 2031

EHDSAllergyIntolerance.certainty		
EHDSCondition.code		26 March 2031
EHDSCondition.onsetDate EHDSCondition.endDate	If the actual date is not known, an estimated date shall be registered in all cases where an estimate can be provided with at least a year precision.	26 March 2031
EHDSCondition.bodySite		26 March 2033
EHDSDevice.udiCarrier EHDSDevice.manufacturer EHDSDevice.name EHDSDevice.type		26 March 2033
EHDSProcedure.code EHDSProcedure.procedureDate[x] EHDSProcedure.bodySite		26 March 2031