Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2022/0140(COD)	Awaiting Council's 1st reading position
European Health Data Space Subject 1.20.09 Protection of privacy and data protection 2.80 Cooperation between administrations 3.30.06 Information and communication technologies, digital technologies 4.20 Public health 4.20.05 Health legislation and policy Legislative priorities Joint Declaration 2023-24 Joint Declaration 2022		

Key players

European Parliament

Joint Committee Responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		31/01/2023
Civil Liberties, Justice and Home Affairs		31/01/2023
	SOKOL Tomislav	
	TARDINO Annalisa	
	Shadow rapporteur	
	ZARZALEJOS Javier	
	CERDAS Sara	
	VITANOV Petar	
	SOLÍS PÉREZ Susana	
	ĎURIŠ NICHOLSONOVÁ Lucia	
	BREYER Patrick	
	METZ Tilly	
	KEMPA Beata	
	KOPCIŃSKA Joanna	
	LIMMER Sylvia	

		ARVANITIS Konstantinos KONEČNÁ Kateřina	
	LIBE Environment, Public Health and Food Safety Civil Liberties, Justice and Home Affairs		
	Committee for opinion	Rapporteur for opinion	Appointed
	BUDG Budgets	The committee decided not to give an opinion.	
	ITRE Industry, Research and Energy (Associated committee)	BUŞOI Cristian-Silviu	09/06/2022
	IMCO Internal Market and Consumer Protection (Associated committee)	KOVATCHEV Andrey	08/07/2022
Council of the European Union			
European Commission	Commission DG Health and Food Safety	Commissioner KYRIAKIDES Stella	
European Economic and Social Committee			

Key events

03/05/2022	Legislative proposal published	COM(2022)0197	Summary
06/06/2022	Committee referral announced in Parliament, 1st reading		
16/02/2023	Referral to associated committees announced in Parliament		
16/02/2023	Referral to joint committee announced in Parliament		
28/11/2023	Vote in committee, 1st reading		
05/12/2023	Committee report tabled for plenary, 1st reading	A9-0395/2023	Summary
12/12/2023	Debate in Parliament		
13/12/2023	Decision by Parliament, 1st reading	T9-0462/2023	Summary
13/12/2023	Matter referred back to the committee responsible		
09/04/2024	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE760.905 GEDA/A/(2024)001744	
24/04/2024	Results of vote in Parliament		

24/04/2024	Decision by Parliament, 1st reading	T9-0331/2024	Summary

Technical information

Procedure reference	2022/0140(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 59; Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 016-p2; Rules of Procedure EP 57_o
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	CJ43/9/11202

Documentation gateway

Legislative proposal		COM(2022)0197	03/05/2022	EC	Summary
Document attached to the procedure		SEC(2022)0196	04/05/2022	EC	
Document attached to the procedure		SWD(2022)0130	04/05/2022	EC	
Document attached to the procedure		SWD(2022)0131	04/05/2022	EC	
Document attached to the procedure		SWD(2022)0132	04/05/2022	EC	
Committee of the Regions: opinion		CDR3754/2022	08/02/2023	CofR	
Committee draft report		PE742.387	10/02/2023	EP	
Amendments tabled in committee		PE745.527	29/03/2023	EP	
Amendments tabled in committee		PE745.528	29/03/2023	EP	
Amendments tabled in committee		PE745.529	29/03/2023	EP	
Amendments tabled in committee		PE745.530	29/03/2023	EP	
Amendments tabled in committee		PE745.531	29/03/2023	EP	
Amendments tabled in committee		PE745.532	29/03/2023	EP	
Amendments tabled in committee		PE745.533	05/04/2023	EP	
Amendments tabled in committee		PE745.471	05/04/2023	EP	
Committee opinion	ITRE	PE742.310	23/05/2023	EP	
Committee opinion	IMCO	PE740.773	25/05/2023	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0395/2023	05/12/2023	EP	Summary
Text adopted by Parliament, partial vote at 1st reading/single reading		T9-0462/2023	13/12/2023	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2024)001744	22/03/2024	CSL	
Text agreed during interinstitutional		PE760.905	22/03/2024	EP	

negotiations					
Text adopted by Parliament, 1st reading/single reading		T9-0331/2024	24/04/2024	EP	Summary
Commission response to text adopted in plenary		SP(2024)394	08/08/2024	EC	

Additional information		
Research document	Briefing	15/09/2022

European Health Data Space

PURPOSE: to establish a European Health Data Space for people and science.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the COVID-19 pandemic has clearly shown the importance of electronic health data for policy-making in response to health emergencies. It has also highlighted the imperative of ensuring timely access to personal electronic health data for health threats preparedness and response, as well as for treatment, but also for research, innovation, patient safety, regulatory purposes, statistical purposes or personalised medicine.

However, the complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially cross-border. At present, individuals have difficulties in exercising their rights with regard to their electronic health data, in particular with regard to accessing and sharing their data nationally and across borders, despite the provisions of the General Data Protection Regulation (GDPR).

The European Health Data Space (EHDS) is the first proposal for a common domain-specific European data space. It will address health-specific challenges to electronic health data access and sharing and will be an integral part of building a European Health Union. EHDS will create a common space where natural persons can easily control their electronic health data. It will also make it possible for researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy.

CONTENT: the proposed regulation has the following objectives:

- to establish the European Health Data Space (EHDS) in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data);

- to improve the functioning of the internal market by establishing a uniform legal framework, in particular for the development, marketing and use of electronic health record systems (EHR systems) in line with EU values.

Primary use of electronic health data

Under the proposal, natural persons should have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form. They should easily share such data with other health professionals within and between Member States in order to improve the delivery of health care.

Member States should ensure that patient records, electronic prescriptions, medical imaging images and reports, laboratory results and hospital discharge reports are issued and accepted in a common European electronic health record exchange format. Categories of electronic health data could be added by means of delegated acts.

When processing data in electronic format, health professionals would have access to the electronic health data of their natural person patients, regardless of the Member State of affiliation and the Member State of treatment.

To safeguard citizens' rights, all Member States should designate digital health authorities. The Commission would set up a central platform for digital health (MyHealth@EU) to provide services to support and facilitate the exchange of electronic health data between Member States' national contact points for digital health.

Interoperability and security

The proposal provides for the implementation of a mandatory self-certification scheme for EMR systems, under which EMR systems must comply with essential interoperability and security requirements. Manufacturers of electronic health record systems will have to certify compliance with these standards. This will ensure that different electronic health record systems are compatible and allow for easy transmission of electronic health data between them.

Improving the use of health data for research, innovation and policymaking

The EHDS creates a strong legal framework for the use of health data for research, innovation, public health, policy-making and regulatory purposes. Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data, crucial to develop life-saving treatments, vaccines or medical devices and ensuring better access to healthcare and more resilient health systems.

To access this data, researchers, companies or institutions would have to apply for authorisation from the body responsible for access to health data, which will have to be set up in each Member State. Access would only be allowed if the requested data are used for specific purposes, in closed and secure environments and without revealing the identity of individuals. Any attempt to use the data for any measures detrimental to the natural person, to increase insurance premiums, to advertise products or treatments, or develop harmful products should be prohibited.

Member States should designate one or more health data access points responsible for granting access to electronic health data for secondary use. The Health Data Access Bodies would be connected to the new EU decentralised infrastructure for secondary use of data (HealthData@EU), which will be set up to support cross-border projects.

BUDGETARY IMPLICATIONS: the fulfilment of the obligations by the Commission and associated support actions under this legal proposal will require EUR 220 million between 2023 and 2027 and will be funded directly from the EU4Health programme (EUR 170 million) and supported further from the Digital Europe Programme (EUR 50 million). In both cases, the expenditure linked to this proposal will be covered within the programmed amounts of these programmes.

European Health Data Space

The Committee on the Environment, Public Health and Food Safety and the Committee on Civil Liberties, Justice and Home Affairs jointly adopted the report by Tomislav SOKOL (EPP, HR) and Annalisa TARDINO (ID, IT) on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.

The aim of the proposed regulation is to establish the European Health Data Space (EHDS) in order to:

- improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data);

- better achieve as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data).

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Rights of natural persons in relation to the primary use of their personal electronic health data

Access to EHR for primary use should be strictly limited to healthcare providers. Where they process data in an electronic format, health professionals should have access, based on the data minimisation and purpose limitation principles, to the electronic health data of natural persons under their treatment and exclusively for the purpose of that treatment, including relevant administration, irrespective of the Member State of affiliation and the Member State of treatment.

Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals should not be informed of the restricted content of the electronic health data without prior explicit consent the natural person.

Priority categories of personal electronic health data for primary use

The right of access should cover: patient records; electronic prescriptions; laboratory results; medical test results and other complementary and diagnostic results; discharge reports; patient discharge reports; medical directives of the natural persons and information about consent for substances of human origin and organ donations.

The patient summary should be harmonised across Member States and include a minimum data set that can be expanded to include disease-specific data. Prescription, dispensation and administration of current and past medications across the continuum of care, including, hospital and ambulatory/day hospitals.

The Commission should, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data. The Commission should ensure that those implementing acts contain the latest versions of healthcare coding systems and nomenclatures and that they are updated regularly in order to keep up with the revisions of the healthcare coding systems and nomenclatures.

Registration of personal electronic health data

When health data are registered or updated, electronic health records should identify the health professional, time and health care provider that carried out the registration or the update. Member States may provide for other aspects of data registration to be recorded.

Right to an effective judicial remedy against a health data access body

Without prejudice to any other administrative or non-judicial remedy, each natural or legal person should have the right to an effective judicial remedy against a legally binding decision of a health data access body concerning them. Proceedings against a health data access body should be brought before the courts of the Member States where the health data access body is established.

Conformity assessment of EHR systems

In order to certify the conformity of an EHR system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator should apply for a conformity assessment procedure. Only after an Union wide approval has been issued, may the CE marking be affixed, together with an identification number.

Minimum categories of electronic data for secondary use

Natural persons should have the right to opt-out of the processing of their electronic health data for secondary use. Member States should provide for an accessible and easily understandable opt-out mechanism, whereby natural persons should be offered the possibility to explicitly express their wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes.

Intellectual property rights and trade secrets for secondary use

Electronic health data entailing protected intellectual property and trade secrets from health data holders should be made available for secondary use. In this case, a specific procedure should apply.

Prohibited secondary use of electronic health data

Members call for rules to prohibit the processing of such data for the following purposes:

- taking decisions which are detrimental to an individual or a group of individuals and which are likely to have legal, economic or social effects;

- taking decisions in relation to a natural person or groups of natural persons in relation to job offers or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans;

- advertising or marketing activities;

- automated individual decision-making, including profiling.

Health data access body

Member States should need to designate one or more health data access bodies responsible for granting access to electronic health data for secondary use.

Member States should ensure that designated separate structures are set up within health data access bodies for the authorisation of the data permit, on the one hand, and for the reception and preparation of the data set, including anonymisation, pseudonymisation of the electronic health data.

Each health data access body should act with full independence in performing its tasks and exercising its powers in accordance with this Regulation. These bodies should decide on data access applications, including deciding on whether the data should be made accessible in anonymised or pseudonymised form, based on its own thorough assessment of any reasons provided by the health data applicant.

The data access body should only issue an authorisation for data processing if all the conditions set out in this Regulation are met.

Natural and legal persons should have the right to: (i) lodge a complaint, individually or, where relevant, collectively, with the health data access body; (ii) have the data processed by the health data access body reviewed.

Right to receive compensation

Any person who has suffered material or non-material damage as a result of an infringement of this Regulation should have the right to receive compensation. Where a natural person considers that their rights under this Regulation have been infringed, they should have the right to mandate a not-for-profit body, organisation or association to lodge a complaint on their behalf.

European Health Data Space

The European Parliament adopted by 516 votes to 95, with 20 abstentions, amendments to the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.

The matter was referred back to the committee responsible for interinstitutional negotiations.

The aim of the proposed regulation is to establish the European Health Data Space (EHDS) in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as to better achieve as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data).

Access to and transmission of personal electronic health data for primary use

Natural persons should have the right to access, immediately, free of charge and in an easily readable, consolidated and accessible format, their personal electronic health data processed in the context of the primary use of electronic health data. They should have the right to request a health data holder in the health or social security sector, or in the reimbursement services, to transmit some or all of their electronic health data to a health data recipient of their choice in the health or social security sector, or in the reimbursement services, immediately and free of charge.

Access to EHR for primary use should be strictly limited to healthcare providers. Where they process data in an electronic format, health professionals should have access, based on the data minimisation and purpose limitation principles, to the electronic health data of natural persons under their treatment and exclusively for the purpose of that treatment, including relevant administration, irrespective of the Member State of affiliation and the Member State of treatment.

Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals should not be informed of the restricted content of the electronic health data without prior explicit consent the natural person.

Priority categories of personal electronic health data for primary use

The right of access should cover: patient records; electronic prescriptions; laboratory results; medical test results and other complementary and diagnostic results; discharge reports; patient discharge reports; medical directives of the natural persons and information about consent for substances of human origin and organ donations.

Personal electronic health data of priority data categories should be delivered across the continuum of care. Member States may provide that individuals have a right to object to the recording of their personal health data in an EMR system.

Right to an effective judicial remedy against a health data access body

Natural and legal persons should have the right to lodge a complaint, individually or, where relevant, collectively, with the health data access body, where their rights are affected. Each natural or legal person should have the right to an effective judicial remedy against a legally binding

decision of a health data access body concerning them. Proceedings against a health data access body should be brought before the courts of the Member States where the health data access body is established.

Conformity assessment of EHR systems

In order to certify the conformity of an EHR system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator should apply for a conformity assessment procedure. Only after an EU wide approval has been issued, may the CE marking be affixed, together with an identification number.

Minimum categories of electronic data for secondary use

Natural persons should have the right to opt-out of the processing of their electronic health data for secondary use. Member States should provide for an accessible and easily understandable opt-out mechanism, whereby natural persons should be offered the possibility to explicitly express their wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes. The amended regulation requires explicit consent to be obtained from a patient for the secondary use of certain sensitive data (e.g. genetic and genomic information).

Intellectual property rights and trade secrets for secondary use

Electronic health data entailing protected intellectual property and trade secrets from health data holders should be made available for secondary use. In this case, a specific procedure should apply.

In this case, health data access bodies should take measures necessary to preserve the confidentiality of such data and to ensure such rights are not infringed.

Prohibited secondary use of electronic health data

Members call for rules to prohibit the processing of such data for the following purposes:

- taking decisions which are detrimental to an individual or a group of individuals and which are likely to have legal, economic or social effects;

- taking decisions in relation to a natural person or groups of natural persons in relation to job offers or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans;

- advertising or marketing activities;

- automated individual decision-making, including profiling.

Health data access body

Member States should designate one or more health data access bodies responsible for granting access to electronic health data for secondary use. They should also ensure that designated separate structures are set up within health data access bodies for the authorisation of the data permit.

Each health data access body should act with full independence in performing its tasks and exercising its powers in accordance with this Regulation. These bodies should decide on data access applications, including deciding on whether the data should be made accessible in anonymised or pseudonymised form, based on its own thorough assessment of any reasons provided by the health data applicant.

The data access body should only issue an authorisation for data processing if all the conditions set out in this Regulation are met.

Natural and legal persons should have the right to: (i) lodge a complaint, individually or, where relevant, collectively, with the health data access body; (ii) have the data processed by the health data access body reviewed.

Right to receive compensation

Any person who has suffered material or non-material damage as a result of an infringement of this Regulation should have the right to receive compensation. Where a natural person considers that their rights under this Regulation have been infringed, they should have the right to mandate a not-for-profit body, organisation or association to lodge a complaint on their behalf.

European Health Data Space

The European Parliament adopted by 445 votes to 142, with 39 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.

The European Parliaments position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

The aim of this Regulation is to establish the European Health Data Space (EHDS) in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as to better achieve other purposes in the healthcare and care sector that would benefit society, such as research, innovation, policy-making, health threats preparedness and response including to prevent and address future pandemics, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data).

Primary use of electronic health data

Natural persons should have the right to give access to or request a healthcare provider to transmit all or part of their electronic health data to another healthcare provider of their choice immediately, free of charge and without hindrance from the health care provider or from the manufacturers of the systems used by that healthcare provider. The Regulation should allow healthcare professionals to consult their patients' files with their consent, even from other EU countries.

The priority categories of personal electronic health data should be the following: patient summaries; electronic prescriptions; electronic dispensations; medical imaging studies and related imaging reports; medical test results, including laboratory and other diagnostic results and

related reports; discharge reports.

Where electronic health data is processed for the provision of healthcare, healthcare providers should register the relevant personal health data falling fully or partially under at least the priority categories in the electronic format in an EHR system.

Member States should ensure that one or more proxy services are established as a functionality of health data access services enabling natural persons to authorise other natural persons of their choice to access their personal electronic health data.

Natural persons should have the right to: (i) insert information in their own HER; (ii) rectify their personal data; (iii) give access to or request a healthcare provider to transmit all or part of their electronic health data to another healthcare provider of their choice immediately, free of charge; (iv) restrict access of health professionals and healthcare providers to all or parts of their personal electronic health data; (v) obtain information, including through automatic notifications, on any access to their personal electronic health data; (vi) refuse to allow their health data to be consulted by practitioners (unless this is necessary to protect the vital interests of the person concerned or of another person).

Health professional access services

For the provision of healthcare, Member States should ensure that access to the priority categories of electronic health data is made available to health professionals, including for cross-border care, through health professional access services. These services should be accessible only to health professionals who are in possession of recognised electronic identification means. The electronic health data in the electronic health records should be presented in a user-friendly manner to allow for easy use by health professionals.

MyHealth@EU

The Commission should establish a central interoperability platform for digital health, MyHealth@EU, to provide services to support and facilitate the exchange of personal electronic health data between national contact points for digital health of the Member States.

Conformity assessment of EHR systems

This Regulation establishes a mandatory scheme of self-conformity assessment for EHR systems processing one or more priority categories of electronic health data should be established to overcome market fragmentation while ensuring a proportionate approach. Through this self-assessment, EHR systems will prove compliance with the requirements on interoperability, security and logging for communication of personal electronic health data established by the two mandatory EHR components harmonised by this Regulation, namely the European EHR systems exchange interoperability component and the European logging component for EHR systems.

The CE marking should be affixed before placing the EHR system on the market.

Secondary use of electronic health data

Data including health records, clinical trials, pathogens, health claims and reimbursements, genetic data, public health registry information, wellness data and information on healthcare resources, expenditure and financing, could be processed for public interest purposes, including research, statistics and policy-making (so-called secondary use).

Secondary use should not be allowed for commercial purposes including advertising, assessing insurance requests or making job market decisions or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans. Access decisions should be made by national data access bodies.

Natural persons should have the right to opt-out at any time and without stating reasons from the processing of personal electronic health data relating to them for secondary use under this Regulation. Member States should provide for an accessible and easily understandable opt-out mechanism to exercise this right, whereby natural persons should be offered the possibility to explicitly express their will not to have their personal electronic health data processed for secondary use.

Transparency

METZ Tilly	Shadow rapporteur	ENVI	14/03/2024	Stichting Onderzoek Multinationale Ondernemingen
METZ Tilly	Shadow rapporteur	ENVI	23/02/2024	European Patients' Forum (EPF)
METZ Tilly	Shadow rapporteur	ENVI	16/02/2024	Standing Committee of European Doctors
SOKOL Tomislav	Rapporteur	ENVI	06/02/2024	Cabinet of Commissioner Kyriakides
SOKOL Tomislav	Rapporteur	ENVI	23/01/2024	Brainlab AG
ZARZALEJOS Javier	Shadow rapporteur	LIBE	11/01/2024	Consejo General de Colegios oficiales de Médicos
ZARZALEJOS Javier	Shadow rapporteur	LIBE	21/11/2023	Farmaindustria
SOKOL Tomislav	Rapporteur	ENVI	15/11/2023	Finnish Institute for

				Health and Welfare
ZARZALEJOS Javier	Shadow rapporteur	LIBE	15/11/2023	Finnish Institute for Health and Welfare (THL)
SOKOL Tomislav	Rapporteur	ENVI	13/11/2023	Belgian Perm Rep
SIPPEL Birgit	Member	26/03/2024	MedTech Europe	
SIPPEL Birgit	Member	12/03/2024	Bundesministerium für Gesundheit	
SIPPEL Birgit	Member	27/02/2024	MedTech Europe	
COLIN-OESTERLÉ Nathalie	Member	21/02/2024	Dassault Systèmes	
LIESE Peter	Member	05/12/2023	Ärztin aus Deutschland	
NIEBLER Angelika	Member	01/12/2023	MedTech Europe	
COLIN-OESTERLÉ Nathalie	Member	08/11/2023	Illumina, Inc.	
SIPPEL Birgit	Member	12/09/2023	MedTech Europe	
TRILLET-LENOIR Véronique	Member	30/05/2023	Health Data Hub / Plateforme des données de santé	
SIPPEL Birgit	Member	09/05/2023	Bayerische Landesärztekammer	