Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2022/0140(COD)	Awaiting committee decision
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 2022	

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	LIBE Civil Liberties, Justice and Home Affairs		
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		
	BUDG Budgets	The committee decided not to give an opinion.	
	IMCO Internal Market and Consumer Protection		08/07/2022
		epp KOVATCHEV Andrey	
	ITRE Industry, Research and Energy		09/06/2022
		epp BUŞOI Cristian-Silviu	
Council of the European Union			
European Commission	Commission DG	Commissioner	
	Health and Food Safety	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		

Technical information

Procedure reference	2022/0140(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation

Legal basis	Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 016-p2
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Awaiting committee decision
Committee dossier	LIBE/9/09027

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	

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.

Transparency

WÖLKEN Tiemo	Member	16/05/2022	Gesundheitsregion EUREGIO
WÖLKEN Tiemo	Member	20/05/2022	AOK Bundesverband