New rights for patients in Europe

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On 5 March 2025 the new European Health Data Space (EHDS) Regulation[2] was published in the Official Journal of the European Union[3]. This is extremely good news for patients, or "natural persons or their representatives" as they are referred to in the regulation. The EHDS establishes rights for natural persons regarding their personal electronic health data, way beyond what the General Data Protection Regulation (GDPR) already affords them. The existing rights are explicitly extended to all health and genetic data related to a person, and new rights are added concerning adding your own information and request the transmission of personal health data, even across borders.

New rights enshrined in 8 articles

Articles 3-10 of the EHDS Regulation set out the rights of individuals with respect to personal electronic health data. These are summarised (by the European Commission) in Figure 1.

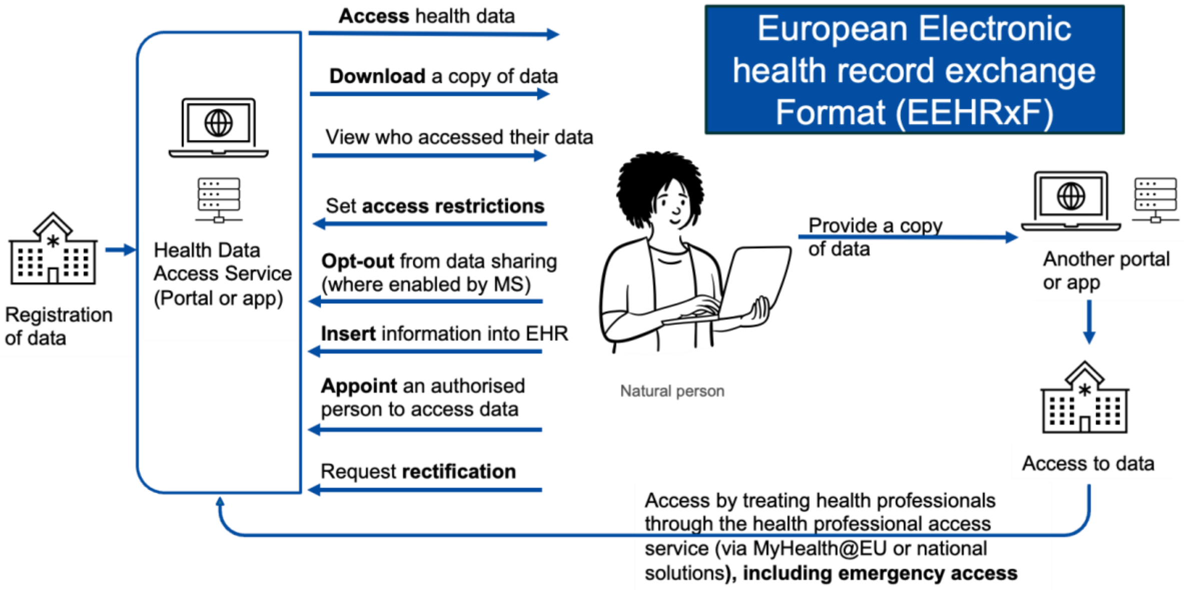

Figure 1: The rights of a natural person regarding their personal electronic health data

New to the EHDS Regulation is that it explicitly specifies the format in which data are accessed and shared: the European Electronic Health Record exchange Format or

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[1] For full details about the author's many affiliations, see https://www.linkedin.com/in/stegwee/

[2] All publications on the EHDS can be found at: https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

[3] Full text available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202500327

EEHRxF[4]. This format enables full (semantic) interoperability of health data across systems used by healthcare professionals as well as the patients themselves.

Exercising your rights

Patients can exercise their rights in three ways:

1. Through the Health Data Access Services (on the left hand side of figure 1) to be set up by each Member State of the European Union – whether this is a centralised service or a service required to be offered by regional or local systems is up to the individual Member State.
2. The right to provide a copy of their personal health data directly to the healthcare provider of their choice. Each healthcare provider (on the right hand side of figure 1) has the obligation to accept these data and be able to read them.
3. By instructing their healthcare provider to make use of the health professional access services (lower part of figure 1) to access or transmit their personal health data from or with another healthcare provider, both national and cross-border (using the MyHealth@EU infrastructure also mandated by the EHDS Regulation).

It is stipulated that these services should be offered free of charge, without delay, and without hindrance from the healthcare provider or from the manufacturers of the systems used by that healthcare provider.

Access to health data

Natural persons shall have the right to access health data immediately after these data have been registered in an EHR system (respecting the need for technical practicability). These data shall be provided in an easily readable, consolidated, and accessible format. There is a provision for Member States to delay this access for a limited period of time, in cases of patient safety or ethical considerations. This is to allow health professionals to properly communicate the information and explain the possible impact on their health.

Download a copy of data

In addition to accessing the data in an easily readable, consolidated, and accessible format, as mentioned above, natural persons also have the right to download a copy of their data in the European EHR exchange Format.

View who accessed their data

Whenever personal health data is accessed through the health professional access services (whether national or cross-border), information on such access shall be made available, including through automatic notifications. This includes the “break-the-glass” functionality provided by the health professional access services to get access to restricted data in cases of emergency. This information shall include the identification of the healthcare provider or other individuals who accessed the information, date and

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[4] For more information on the European EHRxF see: https://ehr-exchange-format.eu/

time of access, as well as the identification of which personal information has beenn accessed.

Set access restrictions

Individuals have the right to restrict the access of healthcare providers and health professionals to all or parts of their personal electronic health data. Of course, an individual exercising this right shall be made aware of the possible consequences this restriction can for the provision of healthcare to them. In addition, these restrictions will not be visible to the healthcare provider.

Opt-out from data sharing

There is quite some difference across EU Member States on the central processing of personal data. Therefore, the EHDS stipulates that a Member State's laws may include the right of individuals to opt out from the electronic data access services, both for individuals and for health professionals. However, the EHDS also stipulates that this shall be a reversible decision.

Insert information to EHR[5]

The Electronic Health Record is defined as a collection of electronic health data related to a natural person and collected in the health system for the purpose of providing healthcare. This right makes the natural person an integral part of the health system, being able to insert information in their own EHR. Of course, the EHDS states that such information should be clearly distinguishable as having been inserted by the person or representative. This links directly to the topic of "provenance" of all data in the collection that is an EHR – who recorded this data and under what circumstances? Such provenance is essential for a valid interpretation of the data in the provision of healthcare. In addition, the right to insert information does explicitly not mean that individuals can change data in the EHR which has been recorded by others. That is the topic of the right to request rectification.

Appoint an authorised person to access data

One feature that is often overlooked in patient portals and apps is the ability to access data and carry out tasks on behalf of someone you care for. This has led to the misuse of identitification and authentication services, where the representative is forced to use the credentials of the patient to accomplish anything. This right seeks to amend that flaw – making sure anyone can appoint their own authorised representative to access (parts of their) data on their behalf. These access rights also extend, without express authorization from the patient, to their legal representatives in accordance with national law. The bonus of the EHDS is that these "proxy services" shall be interoperable across Member States, meaning that you only have to be authorised once to represent the person you care for across the European Union.

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[5] This right is directly related to the topic of Patient Contributed Data (PCD), which is the subject of an HL7 Informative Document: https://www.hl7.org/implement/standards/product_brief.cfm?product_id=638

Request rectification

This right is directly inferred from the General Data Protection Regulation (GDPR). The EHDS makes clear that such request for rectification can be made online through the electronic health data access services mentioned earlier. Also, the controller of the data (i.e. the organisation that determines the purposes and means of the processing of the data) is responsible to respond. It is also the controller's responsibility to verify the accuracy of the information provided in the request with a relevant healthcare professional. This means that the individual does not need to provide "proof" of the accuracy of their request – it is up to the controller to seek such verification.

Provide a copy of data

This right follows directly from the data portibility requirement under the GDPR, but has been made much more explicit in the EHDS Regulation. It is clear that, whenever an individual has downloaded data from the electronic health data access services (in the European EHR exchange Format), they shall be able to transmit that data to a healthcare provider of their choice. The receiving healthcare provider has the obligation to accept such data and make it possible to read them as part of the provision of healthcare services to the individual.

Comparison of EHDS, GDPR and HIPAA

Now how do these rights under the EHDS compare with the fundamental rights of the GDPR and with the Health Insurance Portablity and Accountability Act (HIPAA - a US regulation that also contains provisions for data access and portability). The table below was generated with the help of AI and has been reviewed by experts for correctness.

Right	EHDS	GDPR	HIPAA
Right to Access	Individuals have the right to access their electronic health data, particularly within Electronic Health Records (EHRs)	Individuals have the right to access their personal data and obtain information about how it is being processed	Patients have the right to view their health information and medical records
Right to Data Portability	Expanded right to data portability, allowing individuals more control and ability to mobilize their electronic health data	Individuals have the right to receive their personal data in a structured, commonly used, and machine-readable format	Not explicitly mentioned, but patients can obtain copies of their PHI
Right to Rectification	Individuals have the right to request rectification of their electronic health data	Individuals have the right to obtain the rectification of inaccurate personal data	Patients have the right to request corrections to their health information
Right to Erasure (Right to be Forgotten)	Not explicitly mentioned	Individuals have the right to request the erasure of their	Does not establish a right to be forgotten; retention policies are

		personal data under certain conditions	based on legal and medical necessity
Right to Withdraw Consent	Member State laws may provide individuals with the right to opt out of primary use of electronic health data	Individuals have the right to withdraw consent at any time	Patients can request restrictions on the use and disclosure of their PHI
Right to Restriction of Processing	Individuals have the right to restrict access of health professionals or healthcare providers to all or part of their electronic health data	Individuals have the right to restrict the processing of their personal data under certain circumstances	Patients can request restrictions on the use and disclosure of their PHI
Right to Object	Not explicitly mentioned	Individuals have the right to object to the processing of their personal data	Patients can object to certain uses and disclosures of their PHI
Right to Non-Discrimination	Not applicable	Not applicable	Individuals have the right not to be discriminated against for exercising their privacy rights
Data Protection Officer (DPO)	Not explicitly mentioned	Organizations must appoint a Data Protection Officer to oversee GDPR compliance	Covered entities must designate a privacy officer responsible for HIPAA compliance
Breach Notification	Not explicitly mentioned	Breaches must be reported to the supervisory authority within 72 hours	Breaches affecting more than 500 individuals must be reported to the Office for Civil Rights (OCR) within 60 days

Implementing EHDS rights in day-to-day care

Having new rights under the EHDS is, of course, a major milestone for individuals and their representatives in the health systems across the European Union. However, much will depend on the way in which they can exercise these rights in their dealings with individual healthcare provider organisations and with the services that are to be provided by the Member States. The provision of healthcare remains a key responsibility of the Member States, over which the European Union has little power (the well-known "subsidiarity principle" which is key to the Treaty on the European Union[6]).

Personal Health Record

One key question that comes to mind with the rights (and their schematic representation in figure 1) is: Where do the data an individual downloads and shares

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[6] Explained in https://www.europarl.europa.eu/factsheets/en/sheet/7/the-principle-of-subsidiarity

reside? The EHDS does not say anything about this, but one can imagine that just storing these data unprotected in the EEHRxF on your home computer or mobile device is not the preferred option. Personal apps, or even a full-blown personal health record system, are much more likely to be used by the more sophisticated individuals that take a keen interest in their health data. But then the follow-up question arises: are such personal apps or PHR systems part of the definition of EHR systems that are regulated under the EHDS? If so, should they also be connected to the electronic data access services, both for individuals and for health professionals, as mandated by the EHDS? And would these data also be available through the National Contact Point for eHealth for cross-border information sharing by the MyHealth@EU services? The fact that these data held by an individual may contain a copy of the data available to the individual through the electronic health data access services, leads to a complicated mess of copies that may duplicate or contradict each other and might no longer be valid. Something to be solved, among many other questions that have yet to be answered in implementing the EHDS regulation.

xShare Yellow Button

The xShare project[7] seeks to operationalise (parts of) the rights of natural persons under the EHDS. It's vision is "everyone sharing their health data in EEHRxF with a click-of-a-button. The xShare Yellow Button to be featured across health portals and patient apps and allow people to exercise their data portability rights under GDPR." Together with eight adoption sites the xShare project is aiming to implement this vision in local reality (pending the Member State and EU services to be provided in the upcoming years). The xShare Yellow Button enables natural persons to share their health data in European Electronic Health Record Exchange Format (EEHRxF) by offering three main capabilities:

- The download of their health data
- The health data sharing by using a one-time link
- The health data sharing by using a link valid for a period of time

An xShare Yellow Buttion Implementation Guide is being developed as part of the xShare project[8].

Conclusion

The adoption of the European Health Data Space Regulation across the European Union provides enormous momentum to the provision of electronic health data access services to natural persons and their representatives. The ambitions are a logical outcome of the strategy enabling the digital transformation of health and care that the EU has set out in 2018[9]. This strategy clearly identified "empowering citizens" as one of the key goals. Having the rights of citizens to access and share their health data enshrined in EU regulation will pave the way to more focused implementation. There are

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[7] An EU funded research and innovation action, see: https://xshare-project.eu/

[8] See the initial draft version: http://hl7.eu/fhir/ig/xshare-yb/ImplementationGuide/hl7.eu.fhir.xshare-yb

[9] See the EC Communication: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN

still many things to resolve and many challenges to be overcome, but a common purpose through the EHDS Regulation will help us achieve them.