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EPF European Patients Forum

HEALTHCARE PROFESSIONALS LEAFLET

The European Health Data Space is coming! This leaflet introduces the new law and the political expectations. Its real-life functioning will depend greatly on how it is implemented in your country. We therefore invite you to get to know the initiative and contact your national competent authorities to engage in developing national and local solutions that are informed by health professionals' experience. Information will be updated in line with national implementation and further regulation.

CPME has taken an active role during the negotiations at EU level to ensure the EHDS respects patient safety, privacy, medical confidentiality, usability and user-friendliness. We underline that electronic health records and data sharing must first benefit patient care, avoid disruption to workflows and reduce healthcare professionals' time spent with administrative tasks. These objectives should continue to be highlighted during implementation.

What is the European Health Data Space (EHDS)?

The EHDS[1] is a new EU law that aims to provide European citizens more control over their electronic health data recorded in the provision of healthcare (primary use of data). Patients will have new rights to easily manage their data electronically. This law will allow such data to be made available even when being treated or diagnosed in another EU Member State. The EU law further intends to facilitate the re-use of electronic health data for research, innovation and public policy purposes (secondary use of data). Several key aspects of implementation will depend on national legislation and implementation decisions

When and what type of patient data will be made available electronically?

The EHDS will be implemented in phases from March 2027 until March 2031.

The first group of data categories should be available by March 2029.

- Patient summaries[1]
- Electronic prescriptions
- Electronic dispensations

The second group of data categories should be available by March 2031.

- Medical imaging studies
- Medical test results
- Discharge reports

National governments may provide for additional categories of personal electronic health data to be accessed and exchanged for primary use in the EHR system.

[1] 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 (Text with EEA relevance), OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.

Will it benefit healthcare professionals?

Accessing patient information through the EHDS is expected to improve the information available from the patient, allowing you to understand better, for example, the patient's medical history, the medication being taken, the exams that the patient has undergone. This may reduce the duplication of exams and tests, in particular during emergencies, allowing for the continuity of care and improving the provision of health services. It is also intended to include technical solutions that reduce the administrative burden on healthcare professionals such as reducing the need for manually retyping the same information across different software tools.

The EU law foresees that the patient electronic information is presented in the EHR in a user-friendly manner to allow for easy use by health professionals. However, the benefits of EHDS will depend on usable interfaces and efficient integration into clinical workflows.

Will it be mandatory to register patient information electronically due to the EHDS?

The EU law foresees that digitalisation is voluntary. Healthcare providers, including health professionals, should only register patient's information electronically where this is being done already. The EHDS establishes technical standards that are intended to improve interoperability and accessibility of EHRs and the data they contain. It does not create a data pool.

Under EU law, healthcare professionals who are paper based, and not digitalised, may continue to do so. However, when implementing the EU law, national governments may choose to adopt national rules which go beyond this.

How will healthcare professionals access data in the patient's electronic file?

National governments will first need to set up the infrastructure for the health professional access services where the patient electronic information can be accessed, free of charge, by you. Then, you need to have a secure mean of electronical identification to access the platform (e.g. smartcard, digital ID, etc), be licenced to practice medicine and be the treating physician of the patient.

National governments will set out detailed rules of access, including different access rights depending on the profession or the moment to obtain consent from the patient to access the electronic file.

What information is expected to be accessible for healthcare professionals?

Patient information

Patient summaries, electronic prescriptions and electronic dispensations, medical imaging results, medical test results, and discharge reports.

Patient privacy

The patient can restrict all or part of the information that will be available in the electronic file. You should not assume that the information in the file is complete and/or accurate.

Translation to different languages

You will be able to see the information in your own language but bear in mind that the automated translations might be incorrect. Always confirm with the patient relevant key information.

Opted-out information

If your country introduces the right to opt-out through national law, patients can choose to opt-out of sharing their health data for the primary use on the national electronic health data access service. Your country will define the rules of this opt-out mechanism. The healthcare provider[2] will continue to record patients' health information, but neither the patient nor healthcare professionals will be able to access the electronic health data through the EHDS, except in very limited circumstances (e.g. protect vital interests of the patient or a third person). The decision made by patients is reversible. If a patient asks you about this mechanism, you can direct them to the national digital health authority.

How and what can you record in the patient's electronic file?

You will be able to record **relevant** patient information which falls under the six priority categories of data mentioned above. National governments may require other data to be recorded.

The healthcare professional or healthcare provider recording or updating the patient electronic health record is **identified** in that same record, as well as the **time** at which such input or update is carried out. This to ensure a correct tracking of who has access the file, what type of data was available, accessed and when.

In exceptional circumstances, where there is a factual indication that disclosure of this information would endanger the vital interests or the rights of the healthcare professional, this identifying information of the healthcare professional is not provided to those requesting it.

In cross-border cases, the country of treatment must ensure that the registration is done under the identification data of the patient in the country in which the patient is insured (e.g. national identity number, insurance number, etc).

[2] According to Article 3(g) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, a 'healthcare provider' means any natural or legal person or any other entity legally providing healthcare on the territory of a Member State.

What happens to your personal notes in the patient electronic file?

There can be cases in which healthcare professionals wish to note their concerns, impressions, suspicions or questions. These personal notes are not intended to be read by anyone other than the healthcare professional who wrote them. **If they are shared with others, then they are no longer a personal note. This situation will need to be addressed by national governments in the implementation of the EU law.**

What can a healthcare professional control in the patient electronic file?

National governments may decide to give the right to healthcare professionals and healthcare providers to delay access for patients to their electronic file for a limited time for reasons of patient safety or ethical considerations. This would apply, for example, so a healthcare professional is able to properly communicate and explain the information to the patient. It needs to be information which can have a significant impact on the patient's health.

National governments may provide that access to the EHR is allowed by the healthcare professional to protect the vital interests of the patient or another person – the so-called 'break the glass procedure', even if the patient has not consented to sharing the EHR. However, the final approach and how it will be implemented may vary between countries.

- Information you insert in the patient electronic file cannot be altered by the patient or a representative, but the patient can request online for such information to be rectified.
- Information inserted by the patient or a patient representative in the EHR shall be clearly distinguishable from information inserted by you or other healthcare professionals. Patient-provided information may support care but should not automatically be considered clinically validated.
- You can be requested by the patient to transmit all or part of the patient electronic file to another healthcare professional immediately and free of charge.
- You can be requested by the patient to transmit all or part of the patient electronic file to an identified recipient in the social security or reimbursement sector, such as an insurance, immediately and free of charge. This transmission is one-way only. Please ensure that the transfer is done through secure networks which respect patient confidentiality and privacy.

For more information:
www.eu-patient.eu
www.cpme.eu